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Dräger medical

A Dräger and Siemens Company

Setup and Installation Manual

Part Number: 4114976-001
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Narkomed MRI-2 Anesthesia System

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Introduction

Section contents:

Introduction

This manual provides the basic information needed to setup and install a Narkomed MRI-2 Anesthesia Machine. The setup must be performed by, or under, the direct supervision of an authorized Draeger Medical, Inc. representative. The instructions are divided into the following sections:

Section 2 shows how to correctly move the anesthesia machine and lists the precautions that must be observed while the machine is in transit.

Section 3 outlines installation of the vaporizer, breathing circuit components, sensors, and installation of the power supply and power filter.

Section 4 provides instructions for connecting the gas supplies and the precautions to be observed when installing the cylinders and connecting the pipeline supplies.

Section 5 provides instructions for connecting the power supply and filter, connecting the anesthesia machine to electrical power, and verifying correct power-up indication on the machine.

Section 6 provides instructions for testing and performing Periodic Manufacturer's Service (PMS) to ensure that the machine is ready for service.

Section 7 provides a Setup and Imaging Test Protocol that must be performed at initial installation.

Refer to the *Narkomed MRI-2 Operator's Instruction Manual* for cleaning and routine maintenance procedures.

Warnings Warning statements describe procedures that, if not performed correctly, could result in personal injury.

Cautions Caution statements alert service personnel to the possibility of damage to the equipment if a procedure is not performed correctly.

Notes Note statements clarify information that may not be readily obvious, such as a secondary cause and effect.

Warnings and Cautions Specific to the MRI Environment

The following statements apply to locating the anesthesia machine in an MRI environment. Read them carefully before installing, moving, or using the machine:

WARNING: The user of this anesthesia machine must comply with warnings, cautions, and checkout procedures printed on the rear panel. Failure to do so may result in injury to the patient, operator, or others.

WARNING: All the procedures described in this manual require the use of tools only while the Narkomed MRI-2 is out of the scanner room.

WARNING: This anesthesia machine has been tested only with magnets having field strengths of up to 3.0 tesla. Moving the machine near higher strength magnets could result in machine malfunction or unmanageable attractive forces that could lead to serious injury or death.

WARNING: The power supply charger assembly must not be taken into the magnet room. Damage to the equipment, MRI system, or personal injury could result. *See Section 5 for important installation details.*

WARNING: Use only nonmagnetic (aluminum) E-cylinders with this machine. Steel cylinders can cause serious injury or death if brought into an MRI scanning room.

WARNING: Do not place any object on this machine unless it is specifically labeled to be used in an MRI scanning room and on a Narkomed MRI-2 anesthesia system. Objects placed on this machine that are not designed for use with this anesthesia system may be strongly attracted to the magnet and may cause serious injury or death when the machine is used in an MRI scanning room.

WARNING: Always lock the casters after this anesthesia machine has been positioned in the MRI scanner room. Magnetic attractive forces between the magnet and the anesthesia machine may cause unintentional movement of the anesthesia machine if the casters are unlocked.

WARNING: Do not bring any ferromagnetic tools or equipment into the scanning room. Ferromagnetic objects (made of steel, iron, or stainless steel) are strongly attracted to the magnet and can become harmful projectiles.

WARNING: Use only Draeger Medical, Inc. authorized replacement parts and procedures when servicing this anesthesia machine. Do not service this machine while it is in the MRI scanning room. Consult the Narkomed MRI-2 Service Manual before attempting any service or repair.

WARNING: The Narkomed MRI-2 is designed for MRI use only as a system. The user should not assume that individual components of the system can be safely used with MRI scanners.

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Moving the Narkomed MRI-2

Section contents:

Getting the Machine Ready to Move

Prepare the machine so that it can be moved safely:

- unplug the power cord and the cord to the remote battery charger
- disconnect all external hoses
- remove all external monitors and equipment
- remove the absorber system
- if the machine is bolted, use a nonmagnetic screwdriver to release the machine from the rails

WARNING: Do not bring any ferromagnetic tools or equipment into the scanning room. Ferromagnetic objects (made of steel, iron, or stainless steel) are strongly attracted to the magnet and can become harmful projectiles.

Moving the Machine

Perform the following steps to move the anesthesia machine.

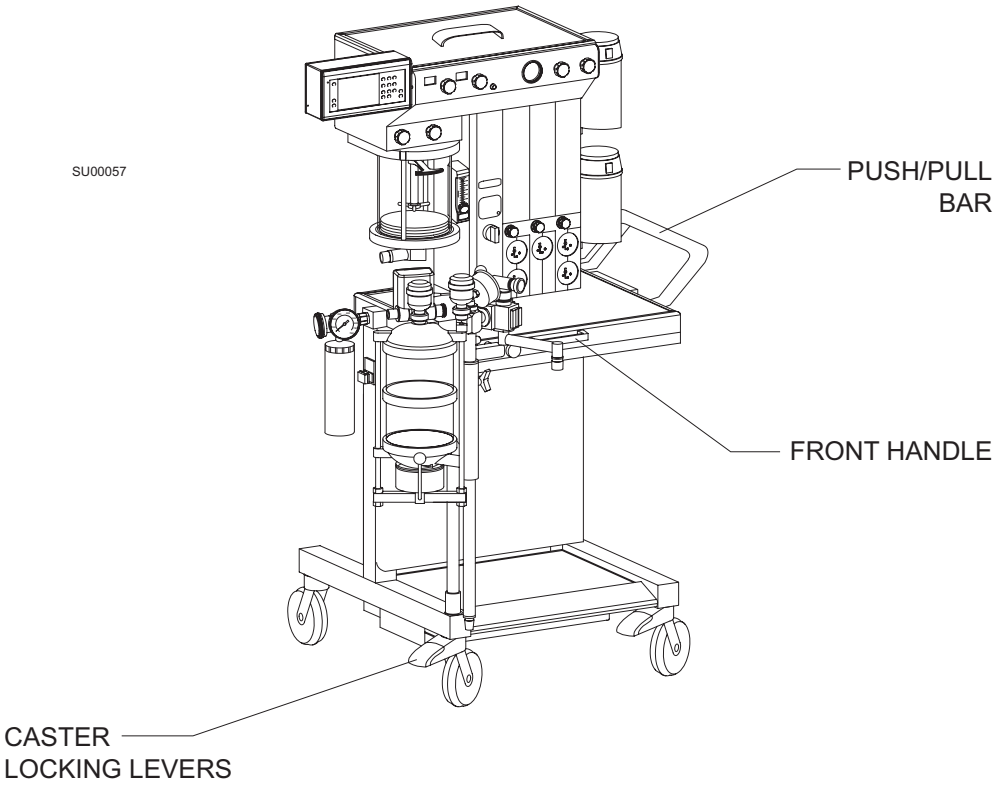
WARNING: When moving the anesthesia machine, remove the absorber system, and use only the machine handles or push/pull bars. The anesthesia machine should only be moved by people who are physically capable of handling its weight. Draeger Medical recommends that two people move the anesthesia machine to aid in maneuverability. Exercise special care so that the machine does not tip when moving up or down inclines, around corners, and across thresholds (for example, in door frames and elevators). Do not attempt to pull the machine over any hoses, cords, or other obstacles on the floor.

1. Unlock the front casters by stepping on their locking levers.

   Do not attempt to move the machine while the casters are locked.

2. Using only the handle or push/pull bar shown in the illustration, move the machine.

   Do not push or pull the anesthesia machine using the absorber system, vaporizers, ventilator bellows, or monitor.


SU00057
PUSH/PULL BAR
FRONT HANDLE
CASTER LOCKING LEVERS

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3

Setup and Installation

Section contents:

Setup Checklist

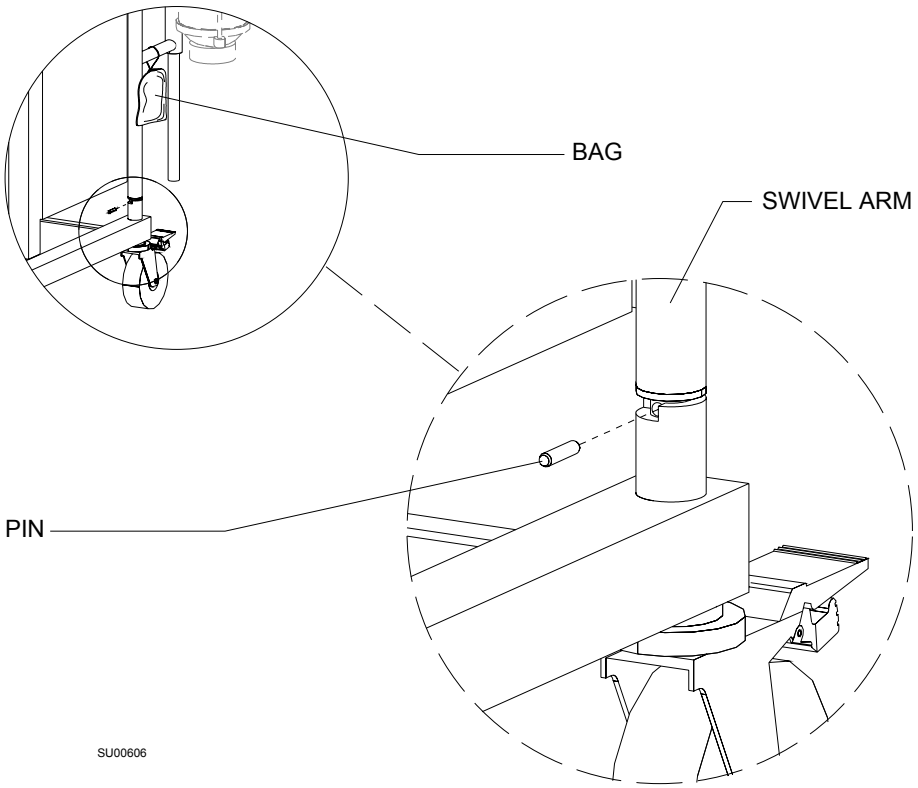
Following is a checklist for the initial setup of a Narkomed MRI-2 anesthesia machine. This setup must be performed by, or under the direct supervision, of an authorized Draeger Medical, Inc. service representative. Items 1 through 14 are described in this section. Items 15 through 18 are outlined in subsequent sections.

1. Install the absorber swivel arm stop pin
2. Install the vaporizers.
3. Install the absorber system.
4. Install the breathing pressure pilot line
5. Install the oxygen sensor.
6. Install the ultrasonic flow sensor.
7. Install the Bain Circuit adapter (optional)
8. Connect the open reservoir scavenger system (optional).
9. Connect the passive scavenger system (optional).
10. Install the suction bottle
11. Connect the battery.
12. Install the power supply filter.
13. Install the power supply.
14. Connect to electrical power.
15. Connect the gas supplies.
16. Power-up diagnostics test.
17. Perform the Periodic Manufacturer's Service (PMS) procedure. This procedure must be performed by an authorized Draeger Medical, Inc. service representative as part of the initial setup.
18. Perform the Setup and Installation Imaging Test Protocol.

Installing the Absorber Swivel Arm Stop Pin

Install the stop pin as follows:

1. Remove the roll pin from the bag hanging on the swivel arm.
2. Rotate the swivel arm so that the hole near the bottom of the arm faces the back of the machine.
3. Hammer the pin into the hole until it is flush with the swivel arm.



Installing the Vaporizers

NOTE: The following restrictions apply to installation of certain types of vaporizers, in order to fill and drain them properly:

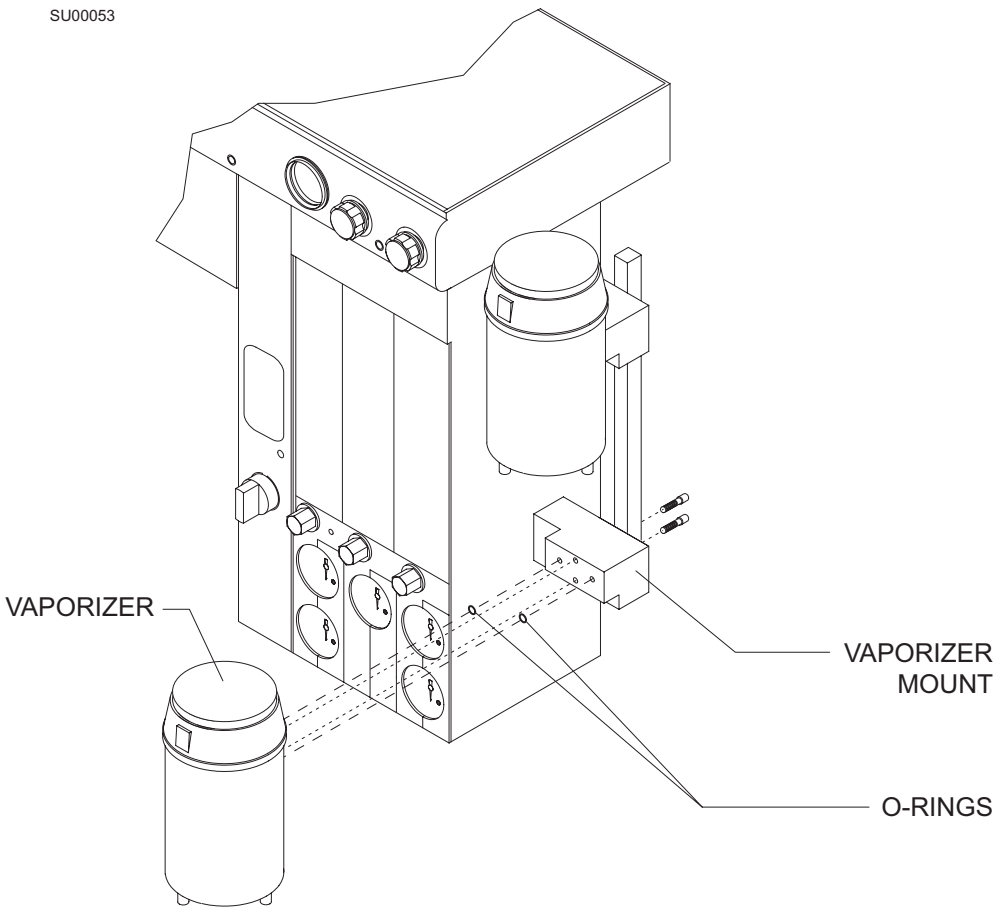
- A Desflurane vaporizer (for non-MRI applications only) shall only be mounted in the upper position.
- A Quik Fil Sevoflurane vaporizer (not approved for use in the USA) shall only be mounted in the upper position.

Vaporizer Installation continued

To install each vaporizer:

1. Remove the vaporizer from its shipping container.
2. Remove the tape from the back of the vaporizer. Verify that the vaporizer has o-rings at the inlet and outlet ports.
3. Unscrew the plastic plate that is mounted over the vapor outlet. Save the screws.
4. Using the screws saved in the previous step, secure the vaporizer to the vaporizer mounting block. Tighten the screws to a torque of 285 N cm (25.25 inch pounds).
5. Test the exclusion system, and perform a leak test on the system. See Section 6.

WARNING: Do not use any screws other than the ones supplied with the vaporizer to secure the vaporizer to the anesthesia machine.



Filling the Vaporizer

See the appropriate separate manual, supplied with vaporizers available for use with the MRI-2.

Handling the Vaporizer

Do not use the vaporizer if it is dropped during handling, if its handwheel spins freely without resistance, or if a gas analyzer maintains a zero reading after the handwheel is turned to a labeled concentration. Return the vaporizer to the Draeger Medical, Inc.'s Technical Service Department.

Installing the Absorber System

This installation procedure presumes the use of an appropriate scavenger system.

WARNING: The Narkomed MRI-2 patient breathing system must not be used with any additional components that establish a flow direction.

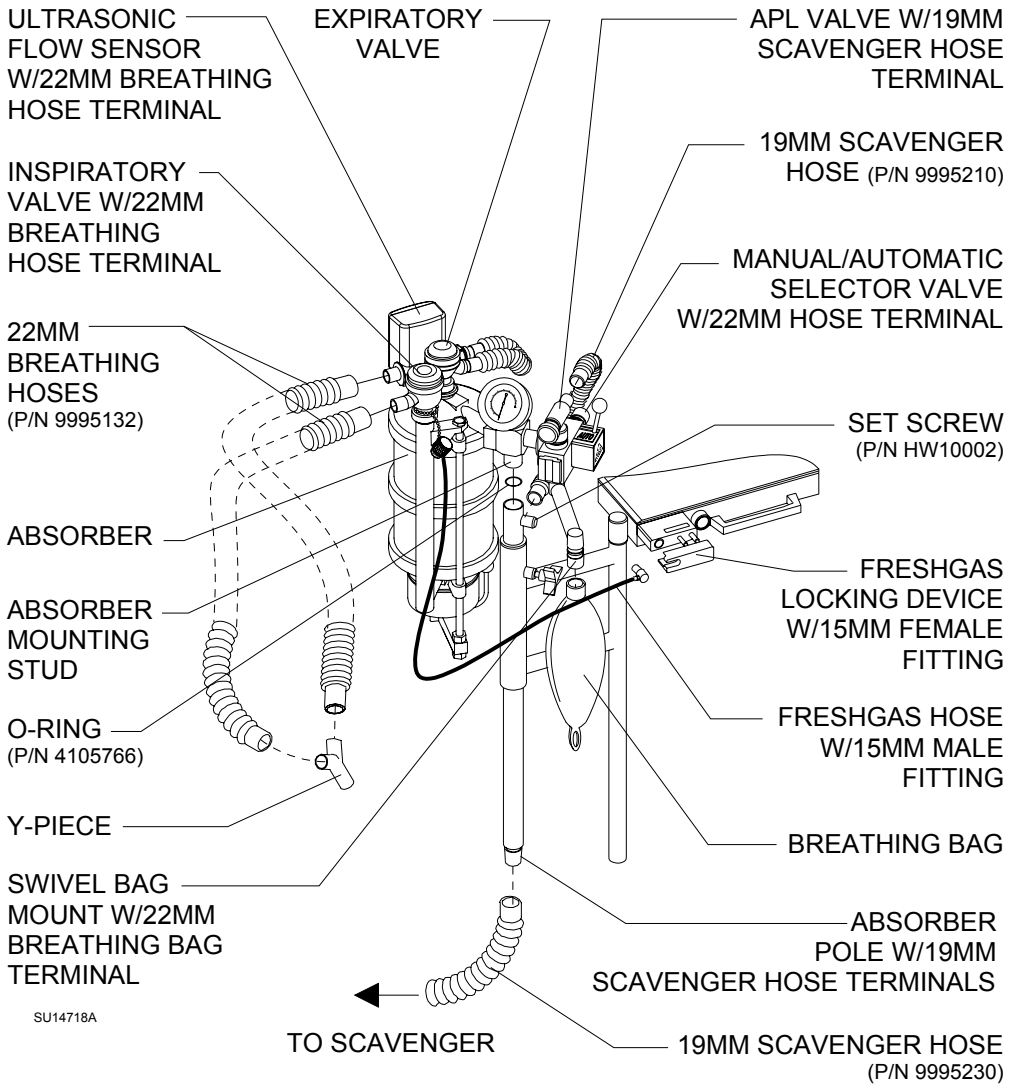
WARNING: Hoses and bags attached to the 22 mm hose terminals of the inspiratory valve, expiratory valve, ventilator hose connection, and breathing bag mount must comply with current ANSI standards.

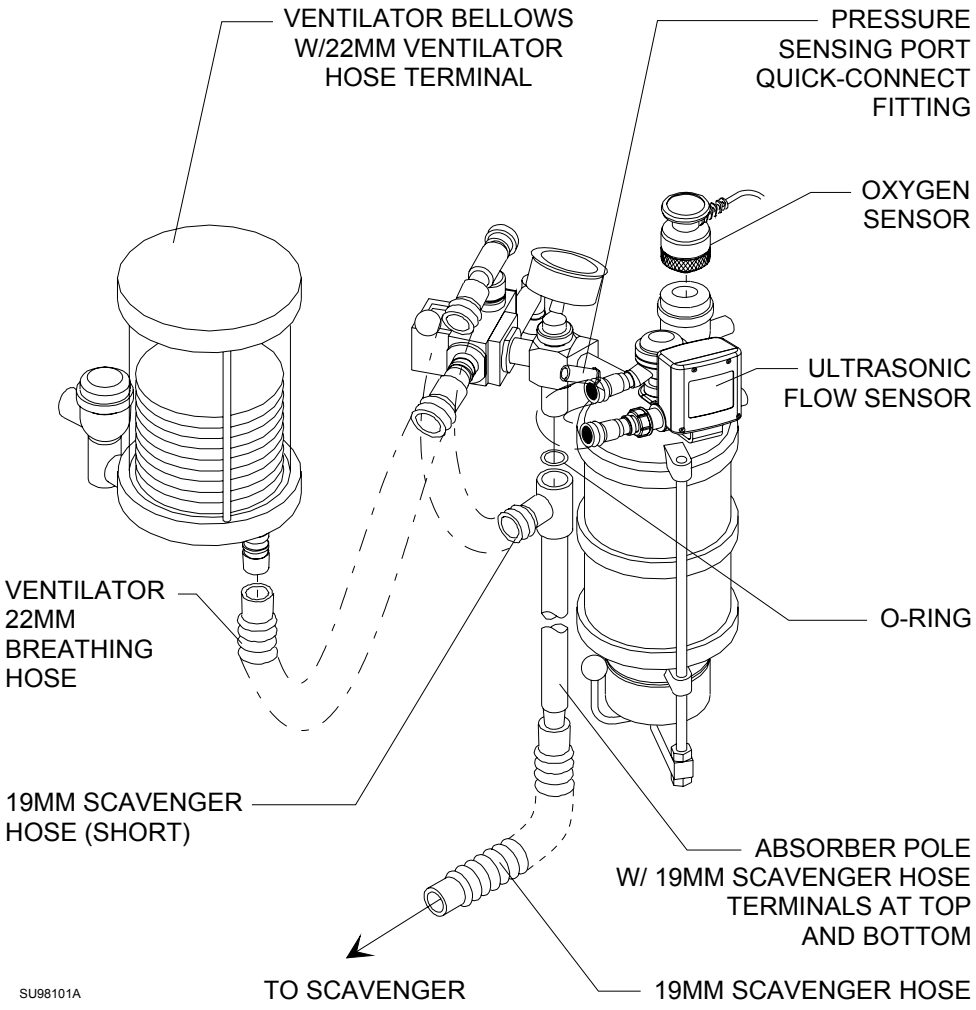
1. Place the absorber mounting stud into the top of the absorber pole. Be sure that the o-ring is on the mounting stud.
2. Tighten the set screw on the absorber pole to lock the absorber in place.

WARNING: Do not pinch or kink the fresh gas hose leading from the fresh gas common outlet to the absorber.

3. Pull out the fresh gas locking bar located on the front of the machine to its extended position. Insert the 15 mm male fitting on the fresh gas hose axially into the 15 mm female terminal. Release the spring-loaded locking bar over the fitting, allowing it to lock the fitting into place.

WARNING: To prevent leaks and misdirection of gas pathways, all hoses should be correctly and tightly fitted as shown in the illustrations. Take special care to make sure that all 19 mm hoses are attached to the proper 19 mm connectors. Possible machine malfunction and harm to the patient can occur if the scavenger hoses are attached to any 22 mm connection.





4. Attach a 22 mm breathing hose between the ventilator bellows 22 mm terminal marked VENTILATOR HOSE, and the 22 mm terminal on the back of the manual/automatic selector valve marked VENTILATOR HOSE.
5. Attach a 22 mm breathing hose between the 22 mm hose terminal on the inspiratory valve marked INSPIRATION and one side of the Y-piece.

WARNING: To ensure proper direction of gas flow during inspiratory and expiratory phases, the disks in the inspiratory and expiratory valves must move freely, without sticking.

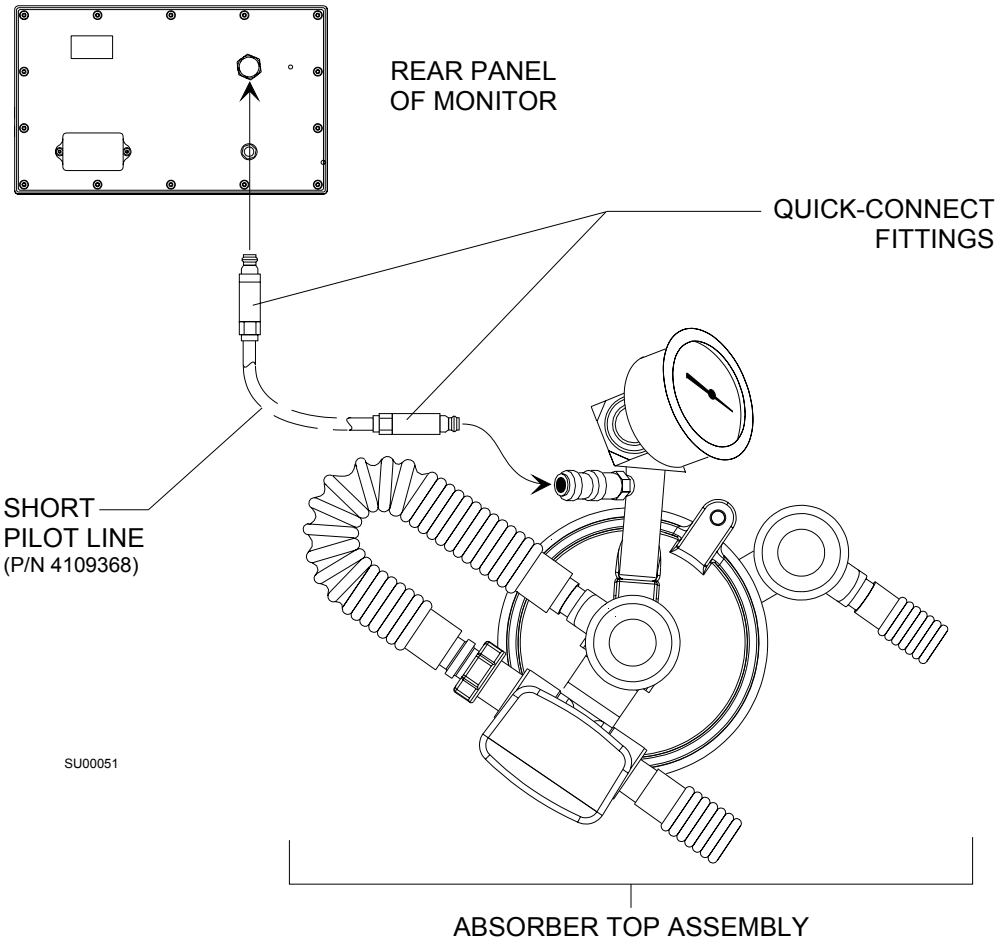
6. Attach a 22 mm breathing hose between the other side of the Y-piece and the 22 mm hose terminal on the expiratory valve marked EXPIRATION.
7. Attach the breathing bag to the swivel bag mount 22 mm terminal marked BREATHING BAG.

WARNING: The breathing bag acts as a pressure-limiting device during manually assisted and spontaneous ventilation. Breathing bags used with the absorber system must comply with the pressure/volume requirements of current ANSI standards. A breathing bag that was previously stretched may have drastically altered compliance characteristics and altered conductivity in the case of conductive bags.

8. Connect the 19 mm scavenger hose between the 19 mm terminal marked SCAVENGER HOSE on the bottom of the absorber pole and the 19 mm terminal marked SCAVENGER HOSE on the scavenger.
9. Connect the 19 mm scavenger hose between the 19 mm terminal marked SCAVENGER HOSE on the back of the APL valve and the 19 mm terminal marked SCAVENGER HOSE on the back of the absorber pole.
10. Test the absorber system for leaks.

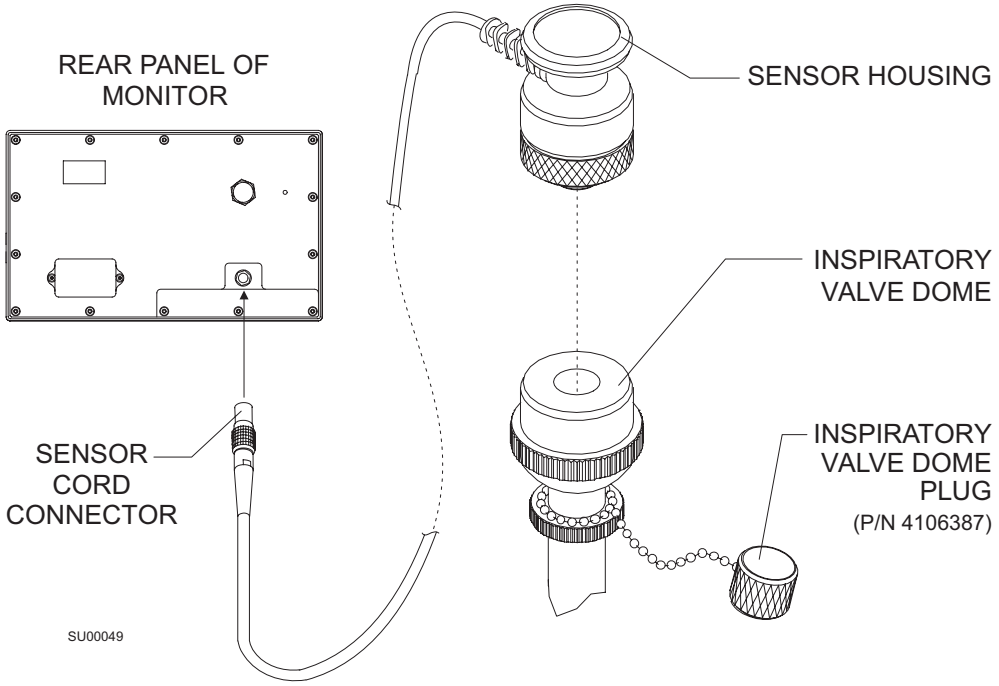
Installing the Breathing Pressure Pilot Line

1. Connect one end of the pilot line to the fitting mounted on the rear of the pipe extending from the absorber top assembly.
2. Connect the other end of the pilot line to the BREATHING PRESSURE fitting on the rear of the monitor.



Installing the Oxygen Sensor

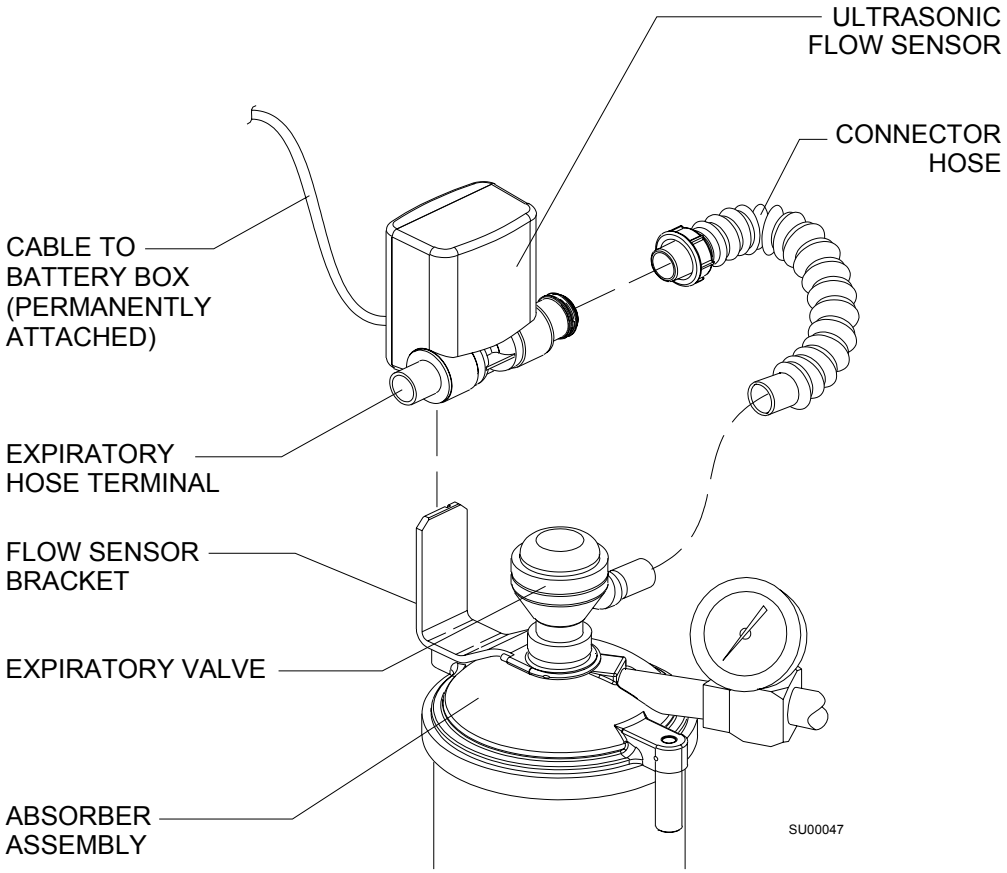
1. Remove the inspiratory valve dome plug from the inspiratory valve dome.
2. Insert the sensor cord connector through the hole in the cord strain relief bracket and into the OXYGEN SENSOR connector on the back of the monitor.
3. Remove any protective covering from the sensor housing.
4. Perform an oxygen sensor calibration as described in the *Narkomed MRI-2 Operator's Manual.*
5. Insert the sensor assembly into the inspiratory valve dome by pressing it into place.



Installing the Ultrasonic Flow Sensor

CAUTION: The ultrasonic flow sensor is permanently wired to the battery box at the bottom of the machine. Do not attempt to un-plug either end of the cable, as damage may result to the assembly.

1. Slide the flow sensor down onto the bracket attached to the expiratory valve mount.
2. Install the connector hose on the threaded port of the flow sensor, and join the other end of the hose to the expiratory valve. Ensure that the expiratory valve is oriented as shown in the illustration below.



Installing the Bain Circuit Adapter (Optional)

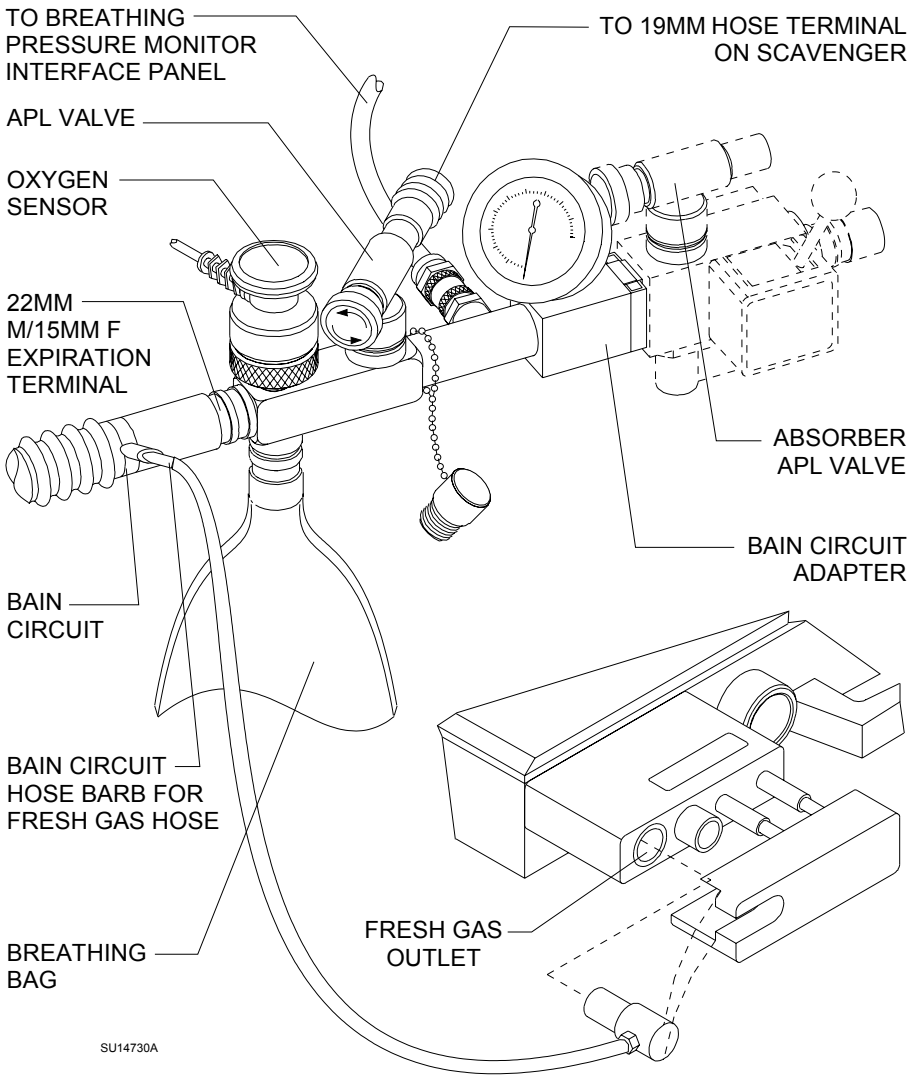
Two types of Bain circuit adapters are available. One mounts to the absorber; the other mounts to the pole.

CAUTION: Only the breathing pressure gauge supplied with a Narkomed MRI-2 Bain circuit adapter should be used.

Absorber Mount

To install the absorber-mounted Bain Circuit Adapter, slip the mounting bracket of the Bain Circuit Adapter down over the slide mount on the absorber assembly (on the block below the APL valve).

WARNING: To avoid confusion between hose terminals on the absorber system and the Bain Circuit Adapter, always remove the Bain Circuit Adapter from the absorber mount when the Bain Circuit Adapter is not in use.

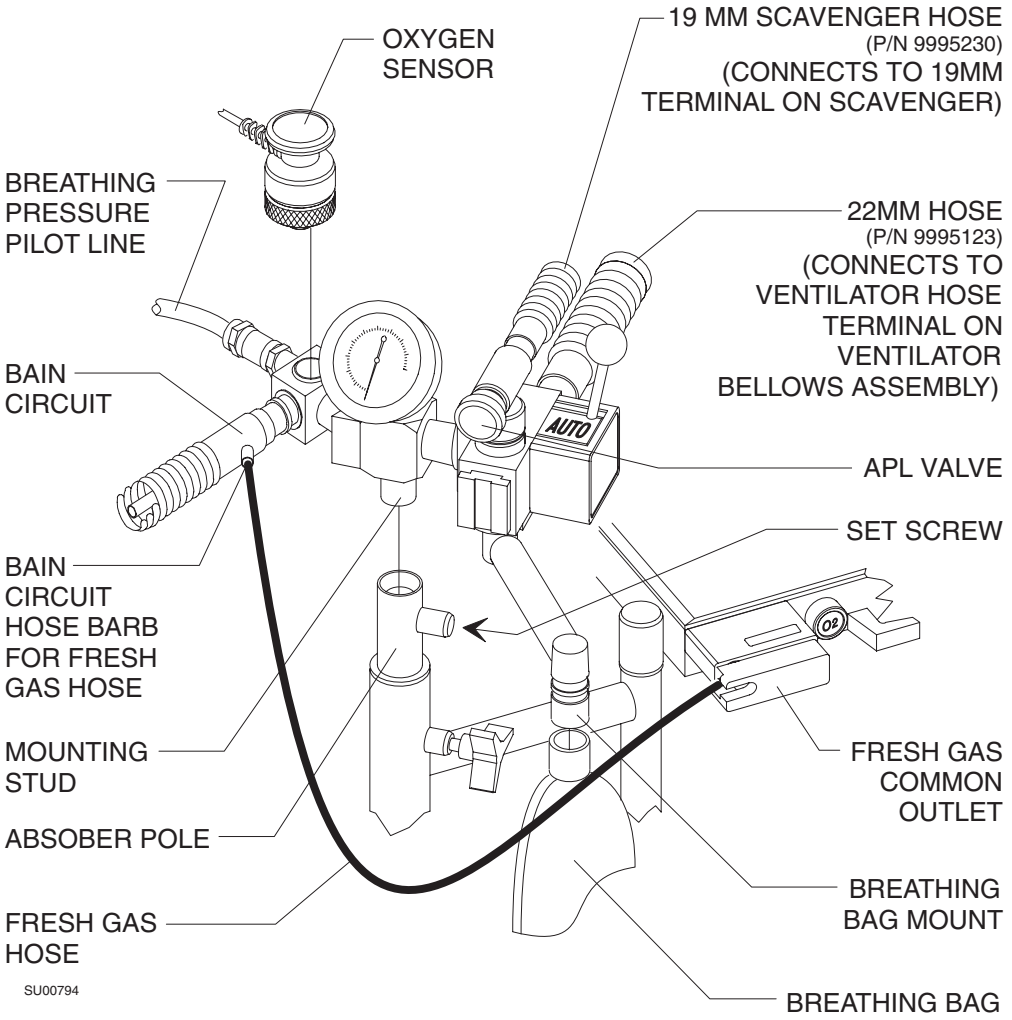


Pole Mount

The pole-mounted Bain Circuit Adapter mounts on the absorber pole.

To install a pole-mounted Bain Circuit Adapter:

1. Loosen the set screw on the absorber pole and remove the absorber system (if the machine is so equipped).
2. Slip the Bain Circuit Adapter mounting stud into the absorber pole.
3. Tighten the set screw on the absorber pole to lock the Bain Circuit Adapter in place.



Bain Circuit Oxygen Sensor Installation

1. Insert the oxygen sensor into the port adjacent to the expiratory terminal. When the port is not in use, close it with the provided plug. Insert the sensor cable into the OXYGEN SENSOR interface as described earlier in this section.

WARNING: A functioning oxygen analyzer must always be used with the Bain Circuit Adapter.

2. Connect the breathing pressure pilot line to the quick-connect fitting on the bain circuit adapter. Insert the other end of the pilot line into the BREATHING PRESSURE interface as described earlier in this section.

WARNING: A functioning breathing pressure monitor must always be used with the Bain Circuit Adapter.

3. Bain Circuit ConnectionsInstall the breathing bag onto the terminal labeled BREATHING BAG.

WARNING: Breathing bags attached to the Bain Circuit Adapter's 22 mm terminals must comply with current ANSI standards.

4. Connect the 19 mm scavenger hose between the 19 mm terminal at the rear of the APL valve marked SCAVENGER HOSE and the 19 mm terminal on scavenger.

5. If applicable, connect a 22 mm hose between the terminal on the rear of the manual/automatic selector valve, and the VENTILATOR HOSE terminal on the bottom of the ventilator bellows assembly.

WARNING: Hoses connected to the Bain Circuit Adapter terminals must comply with current ANSI standards.

6. Connect the Bain Circuit to the 22 mm male/15 mm female terminal on the Bain Circuit Adapter marked EXPIRATION.

7. Connect the fresh gas hose between the fresh gas outlet on the Narkomed GS, and the hose barb fitting on the Bain Circuit (inner tube connection).

8. Set the APL valve fully open and set the Man/Auto selector to BAG.

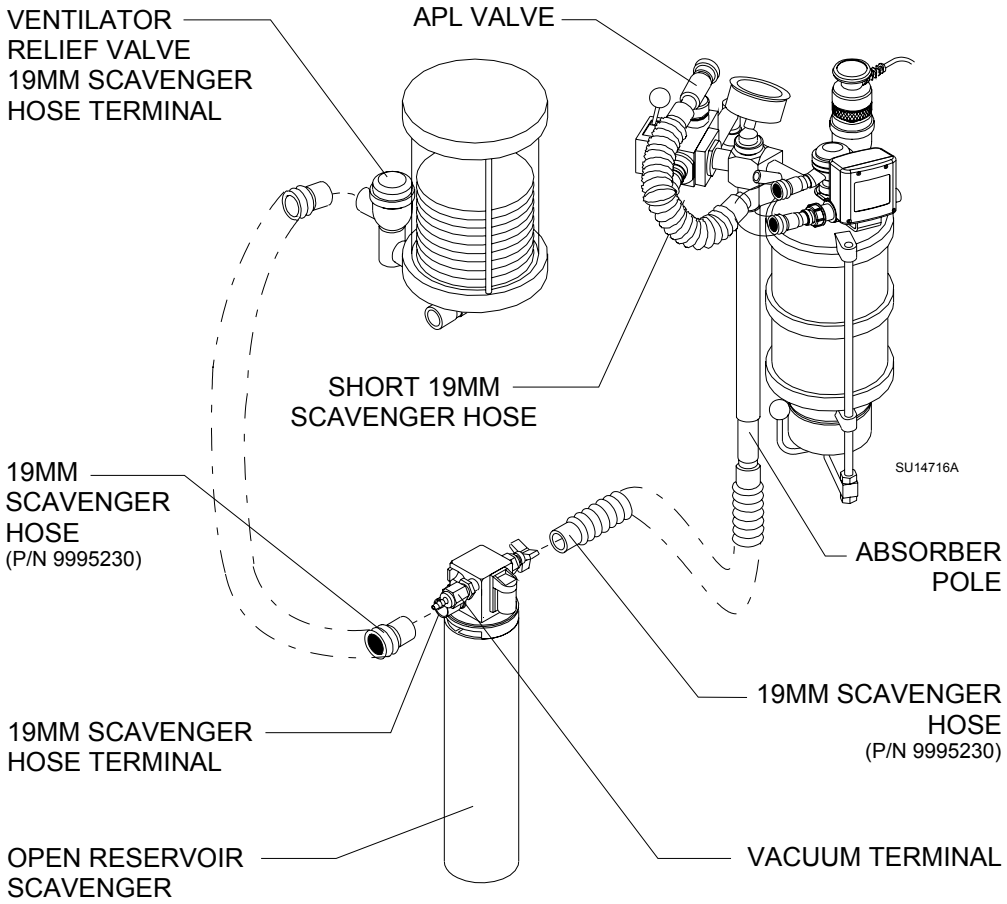
WARNING: The fresh gas hose must not be pinched or kinked.

Connecting the Open Reservoir Scavenger System (Optional)

If ordered, the open reservoir scavenger is installed on the Narkomed MRI-2 before shipping. The scavenger hose connections are described below.

CAUTION: Take special care not to accidentally force 19 mm scavenger hoses over 22 mm breathing hose terminals. Carefully follow the hose connection instructions for installing the scavenger and the absorber.

1. Connect a 19 mm scavenger hose between the 19 mm terminal (marked SCAVENGER HOSE) on the bottom of the absorber pole and the 19 mm terminal (marked SCAVENGER HOSE) on the right side of the scavenger.



WARNING: The 19 mm scavenger hoses leading from the absorber must not be pinched, kinked, or blocked in any manner.

2. Connect the short 19 mm scavenger hose between the 19 mm terminal (marked SCAVENGER HOSE) on the back of the APL valve and the 19 mm terminal (marked SCAVENGER HOSE) on the back of the absorber pole.
3. Connect another 19 mm scavenger hose between the 19 mm terminal (marked SCAVENGER HOSE) on the ventilator relief valve and the 19 mm terminal (marked SCAVENGER HOSE) on the left side of the scavenger.

WARNING: The 19 mm scavenger hose leading from the ventilator relief valve must not be pinched, kinked, or blocked in any manner.

4. Connect a wall suction hose between the wall suction outlet and the suction terminal (DISS fitting or hose barb with adapter) on the scavenger.

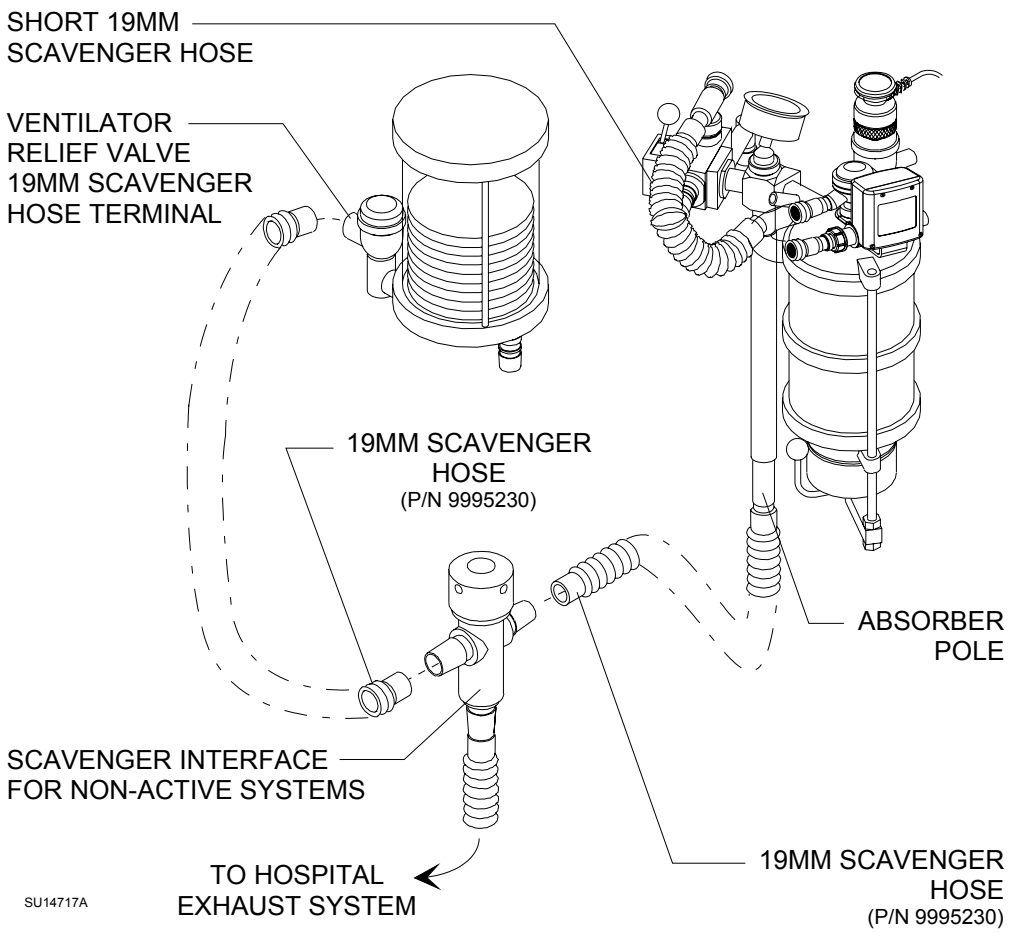
Connecting the Scavenger Interface for Passive Systems (Optional)

If ordered, the scavenger interface for passive systems is installed on the Narkomed MRI-2 before shipping. The scavenger hose connections are described below.

CAUTION: Take special care not to accidentally force 19 mm scavenger hoses over 22 mm breathing hose terminals. Carefully follow the hose connection instructions for installing the scavenger and the absorber.

1. Connect a 19 mm scavenger hose between the 19 mm terminal (marked SCAVENGER HOSE) on the bottom of the absorber pole and the 19 mm terminal (marked SCAVENGER HOSE) on the right side of the scavenger.

WARNING: The 19 mm scavenger hoses leading from the absorber must not be pinched, kinked, or blocked in any manner.



2. Connect the short 19 mm scavenger hose between the 19 mm terminal (marked SCAVENGER HOSE) on the back of the APL valve and the 19 mm terminal (marked SCAVENGER HOSE) on the back of the absorber pole.
3. Connect another 19 mm scavenger hose between the 19 mm terminal (marked SCAVENGER HOSE) on the ventilator relief valve and the 19 mm terminal (marked SCAVENGER HOSE) on the left side of the scavenger.

WARNING: The 19 mm scavenger hose leading from the ventilator relief valve must not be pinched, kinked, or blocked in any manner.

NOTE: If only one of the 19 mm hose terminals will be used, the unused terminal should be capped with the provided input port cap.

4. Connect another 19 mm scavenger hose between the vertical 19 mm terminal labeled EXHAUST and the hospital exhaust system grill adapter.

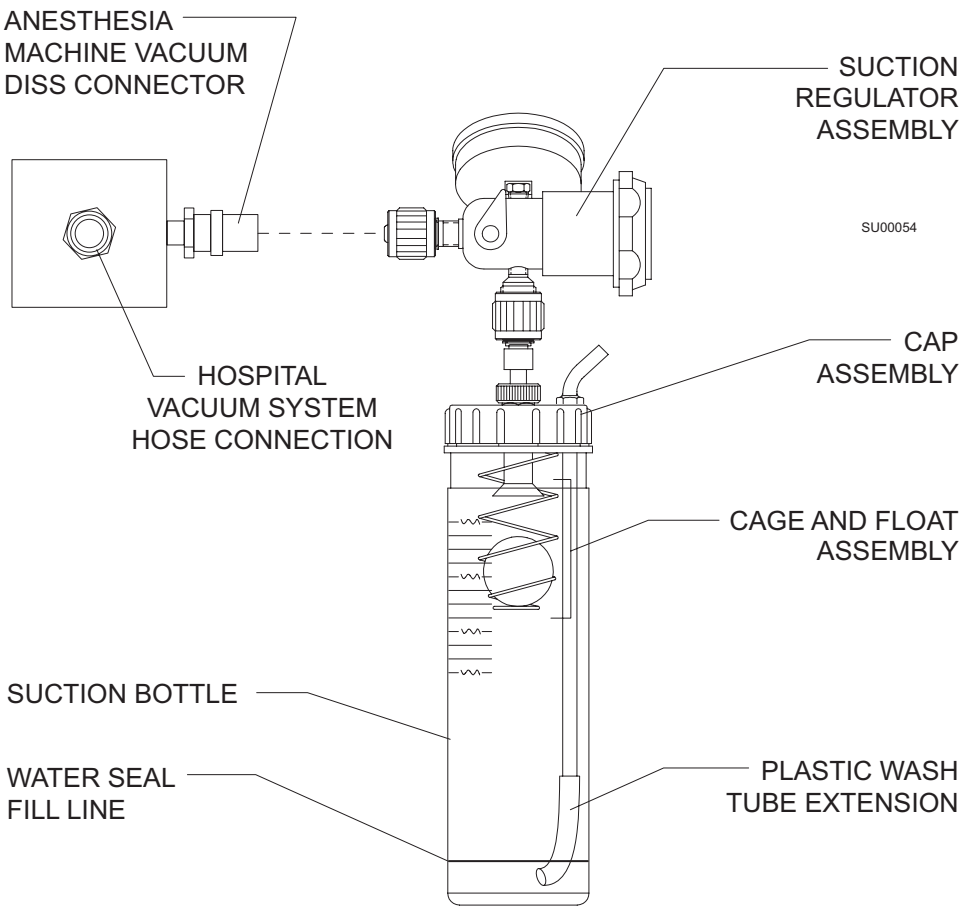
Installing the Suction Bottle

1. Check the cage and float assembly in the suction bottle, and verify that the float ball does not stick in the cage assembly.
2. Connect the suction regulator assembly to the DISS fitting labeled VACUUM on the side of the machine.
3. Fill the suction bottle to the water seal fill line with distilled or sterile water, and thread the bottle into the cap assembly. Make sure that the plastic wash tube extension is below the water level.

NOTE: The water seal arrangement prevents debris from entering the suction regulator.

4. Join the cap assembly and bottle to the suction regulator assembly.
5. Attach a supply hose from the hospital vacuum system to the vacuum connector on the machine.

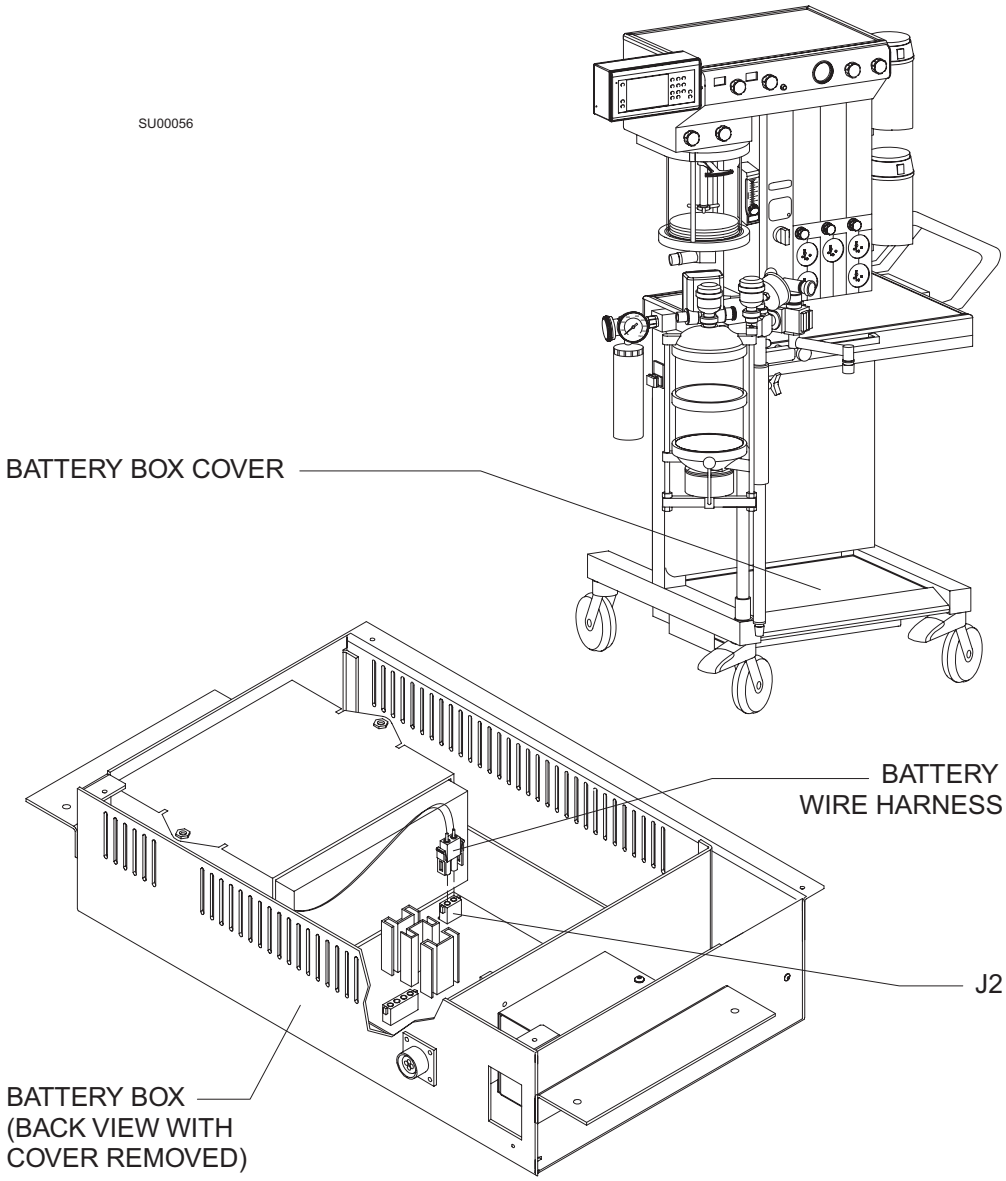
REAR VIEW OF CONNECTIONS



Connecting the Battery

The anesthesia machine is shipped with its battery disconnected in order to prevent discharge during shipment and storage prior to installation. Following are the instructions for connecting the battery:

1. Remove the four screws securing the battery box cover, and remove the cover. Be careful not to damage the attached flow sensor cord.
2. Plug the battery wire harness (yellow and black wires) into J2 on the PCB assembly.
3. Reinstall the battery box cover.



Installing the Power Supply Filter

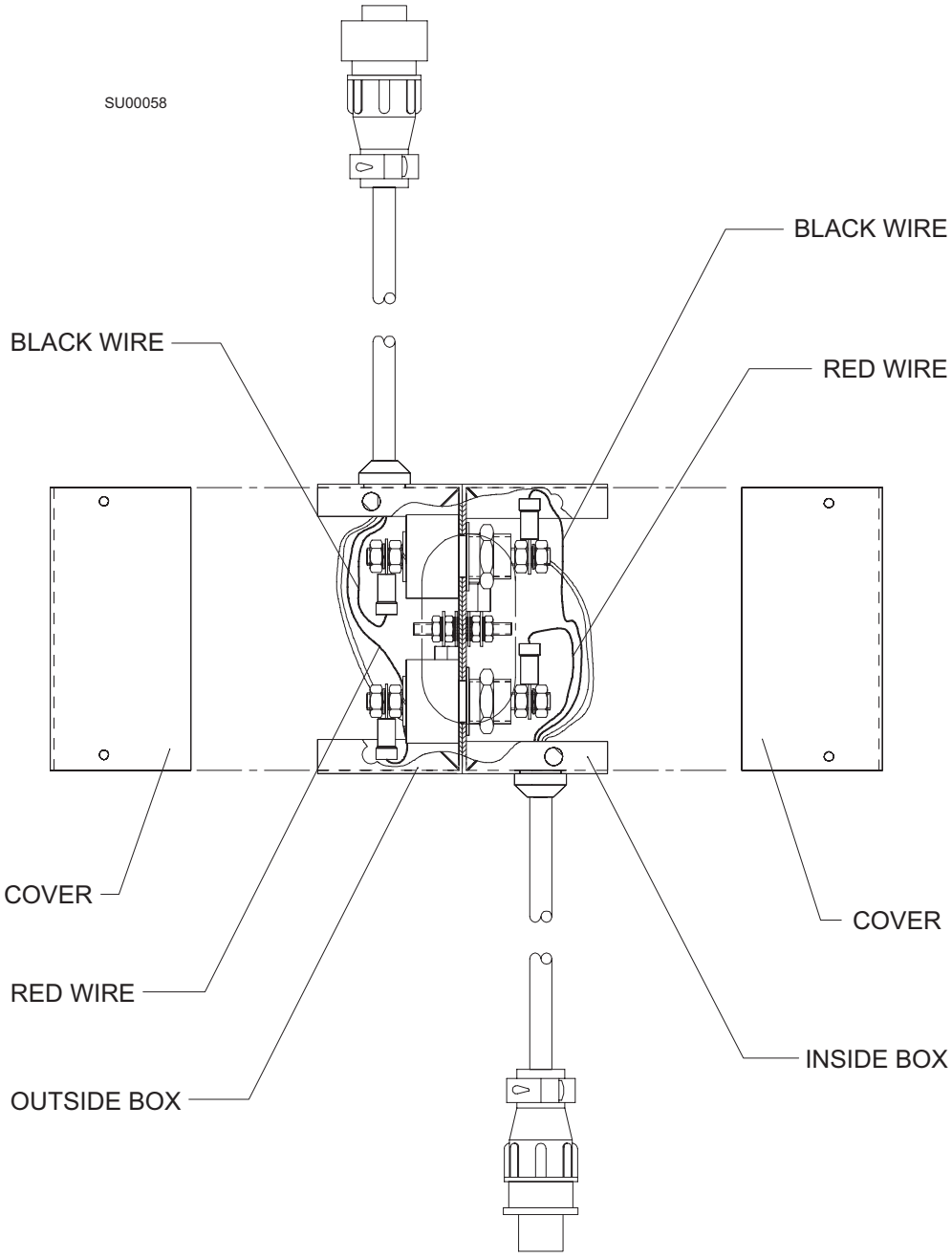
The power supply filter is furnished as a double box assembly that must be re-assembled in a through-the-wall arrangement, in the MRI room access panel as shown in the illustrations on following pages.

WARNING: Do not bring any ferromagnetic tools or equipment into the scanning room. Ferromagnetic objects (made of steel, iron, or stainless steel) are strongly attracted to the magnet and can become harmful projectiles.

1. Remove any shroud covers to expose the access panel on both the inside and the outside of the MRI room. See illustration on next page.
2. Select a suitable location for the filter box on the MRI room access panel. The average access panel has removable plates. A suitable location would be an unused plate on the access panel, or a plate that has sufficient room to easily mount both sides of the filter without disturbing other installed equipment.
3. Remove the selected plate from the access panel and find a suitable place for drilling. Carefully mark and drill two ½ inch holes in the removed plate according to the dimensions given in Detail A on the illustration. Remove any burrs from both sides of the plate.
4. Remove the box covers and the cover screws (located in a bag) from the filter assembly, and disconnect the red and black wires from the inside box filter terminals. DO NOT disturb the ground stud wiring (not shown).
5. Remove the ½-28 nuts and lock washers from the filter bushings, and separate the inside box from the filter box.
6. Re-assemble the boxes as shown in the illustration - with the filter box on the outside of the access panel, and the inside box on the MRI room side of the access panel. Secure the assembly with the lock washers and ½-28 nuts on the filter bushings.

NOTE: The filters and each side of the filter box must be mounted flush on the removable plate to ensure RF integrity.

Filter Box Assembly

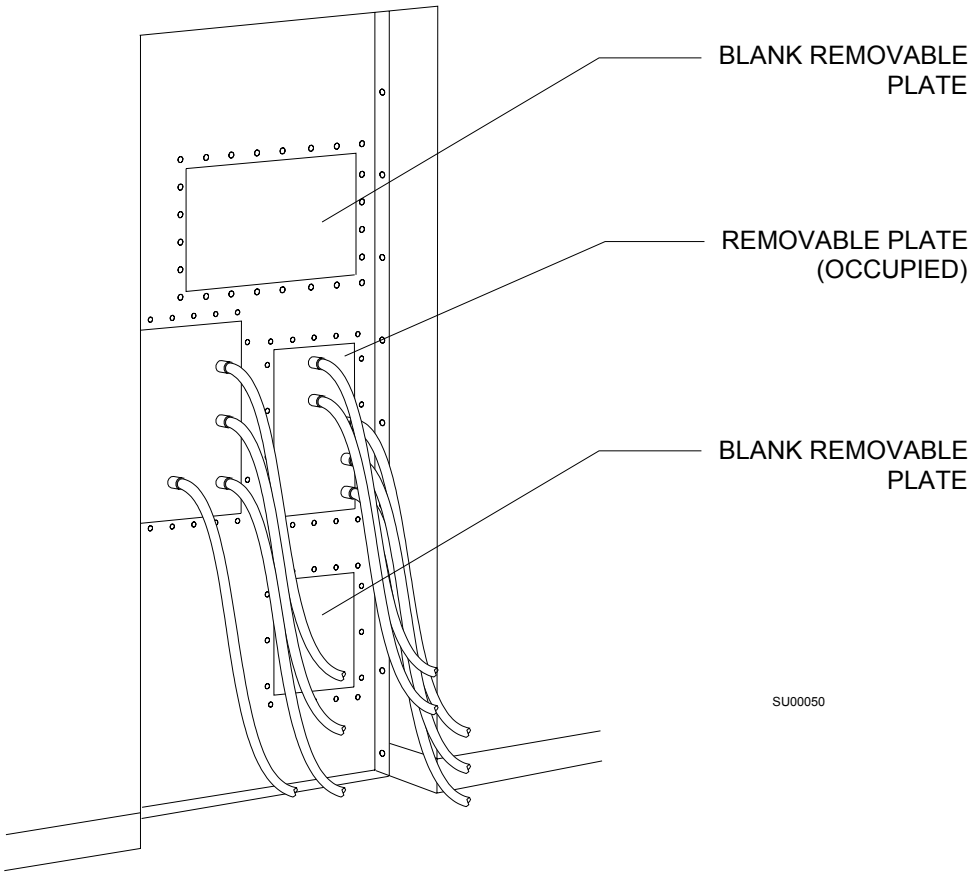


7. Reconnect the red and black wires to the inside box filter terminals.
8. Verify that the red wire in the inside box is connected to the same filter element as the red wire in the outside filter box.
9. Install the covers on both boxes using the hardware found inside the box covers.
10. From outside the MRI room, put the cable with the female connector (from the inside filter box) through the access panel where the plate was removed, and reinstall the assembled filter box and plate back on the access panel where the plate was previously removed.

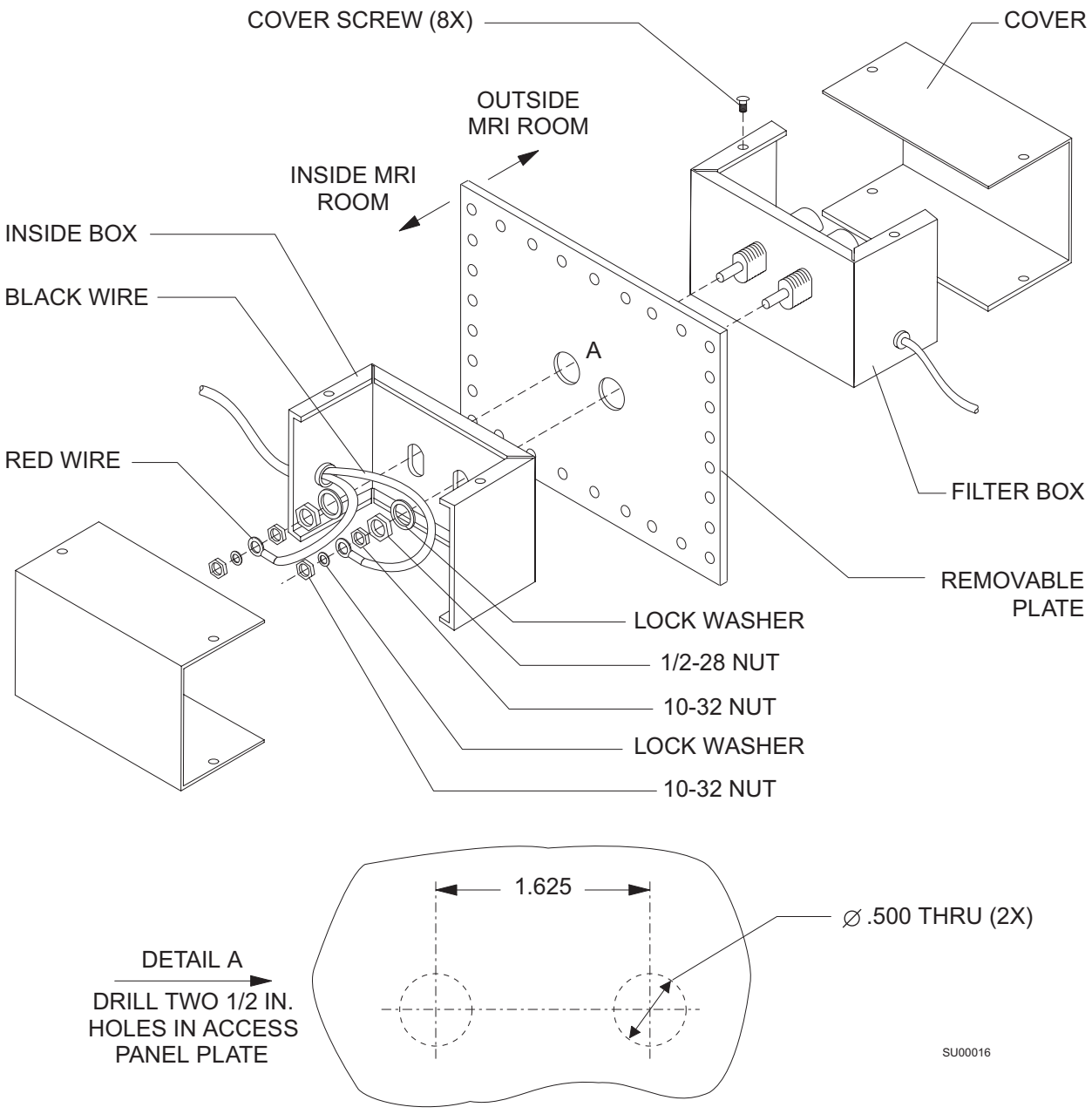
NOTE: All hardware securing the plate to the access panel must be tightly secured.

11. Reinstall any shroud cover inside the MRI room that was previously removed. Ensure that the DC power cable is accessible for connection to the machine's cable.

TYPICAL MRI ROOM
ACCESS PANEL
(SHOWN WITHOUT SHROUD COVER)

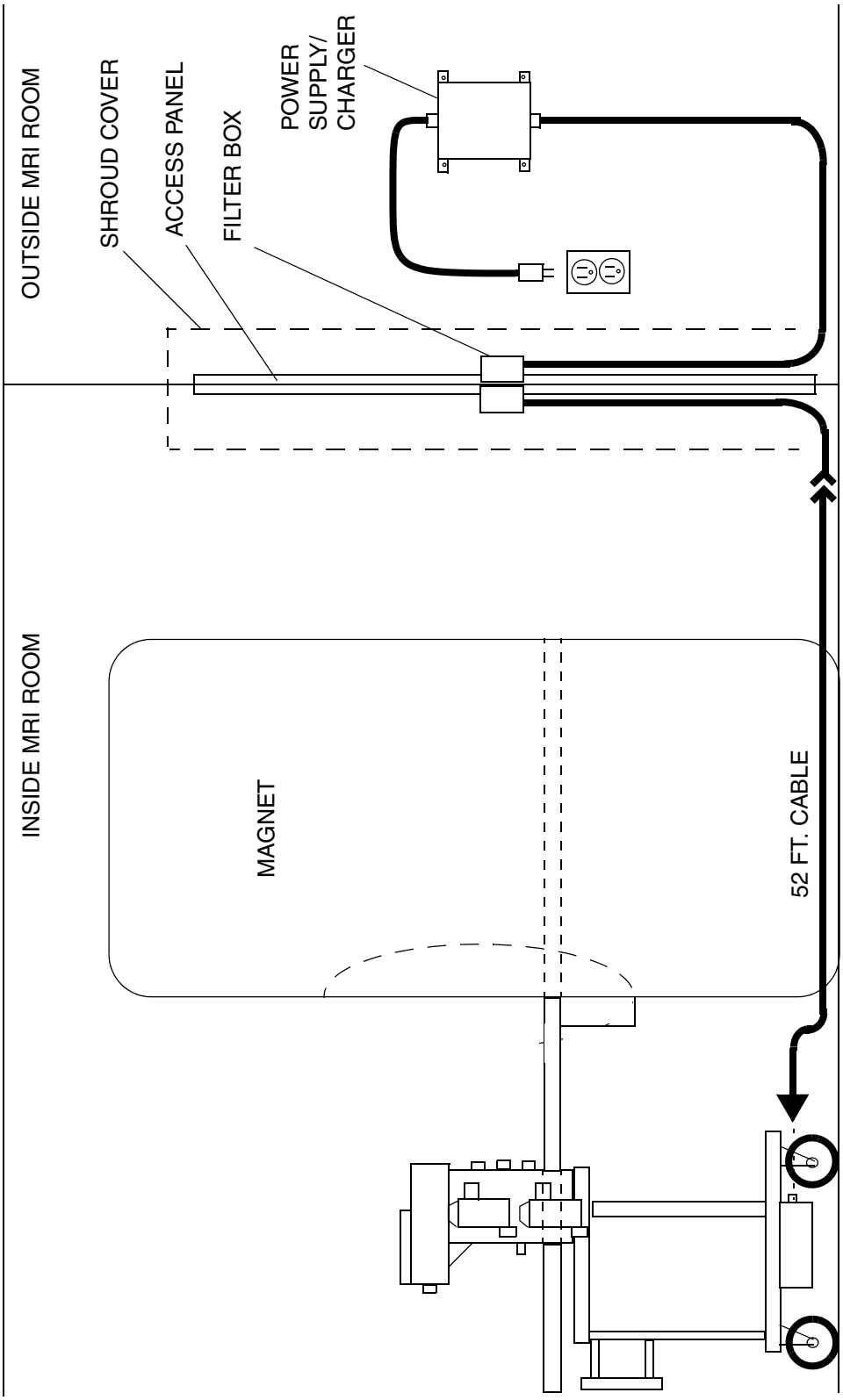


Typical Access Panel Arrangement



Filter Installation Details

MRI-2 Installation Profile



Installing the Power Supply Charger

Select a suitable location for the power supply on the outside wall of the MRI room. The power supply should be located in the vicinity of the previously installed filter box, at a distance that will accommodate the input cable attached to the filter box, and to the nearest AC receptacle.

WARNING: The power supply charger assembly must not be taken into the magnet room. Damage to the equipment, MRI system, or personal injury could result.

WARNING: The power supply charger must not reside in an area where field strength is greater than 50 gauss.

The power supply charger has mounting holes suitable for #8 diameter screws. The type of fastener used will depend upon the wall material at your location. Coordinate mounting of the power supply charger with the MRI or Biomed technician at a location that considers the available cable length from the filter box to the nearest AC receptacle.

1. Hold the power supply charger in place and carefully mark the four mounting hole locations as shown in the illustration.
2. Attach the power supply charger to the wall with four screws. Minimum recommended length is ¼ in.

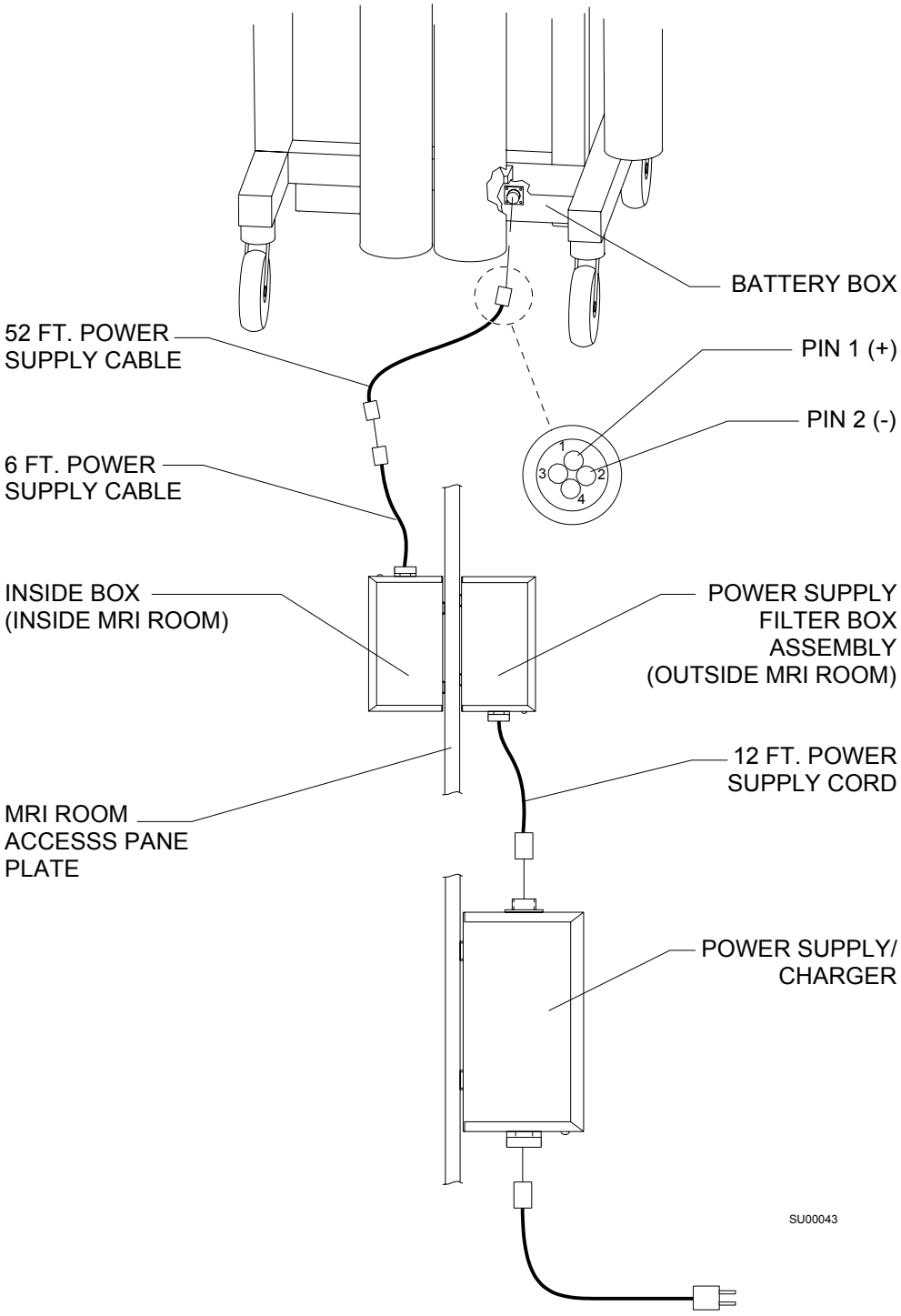
Connecting to Electrical Power

Connect the Narkomed MRI-2 to electrical power as follows:

1. Verify that the SYSTEM POWER switch on the front of the anesthesia machine is set to STANDBY.
2. Disconnect the female end of the 52 ft. cable attached at the rear of the machine.
3. Attach the cable from the filter box to the power supply charger.
4. Connect the AC power cord to the power supply charger, and the opposite end to an AC receptacle.
5. Connect the cable from the inside box of the power supply filter to the end of the 52 ft. cable (see illustration).

Voltage Measurement

6. Measure the voltage between Pin 1 referenced to Pin 2 at the connector on the 52 ft. cable (see illustration on next page). The voltage should be between +13.6 VDC and +14.5 VDC.
7. Connect the female end of the 52 ft. DC power cord to the power inlet connector located at the rear of the machine.
8. Reinstall any shroud cover that was previously removed.


BATTERY BOX
52 FT. POWER SUPPLY CABLE
PIN 1 (+)
PIN 2 (-)
6 FT. POWER SUPPLY CABLE
INSIDE BOX (INSIDE MRI ROOM)
POWER SUPPLY FILTER BOX ASSEMBLY (OUTSIDE MRI ROOM)
12 FT. POWER SUPPLY CORD
MRI ROOM ACCESSS PANE PLATE
POWER SUPPLY/ CHARGER
SU00043

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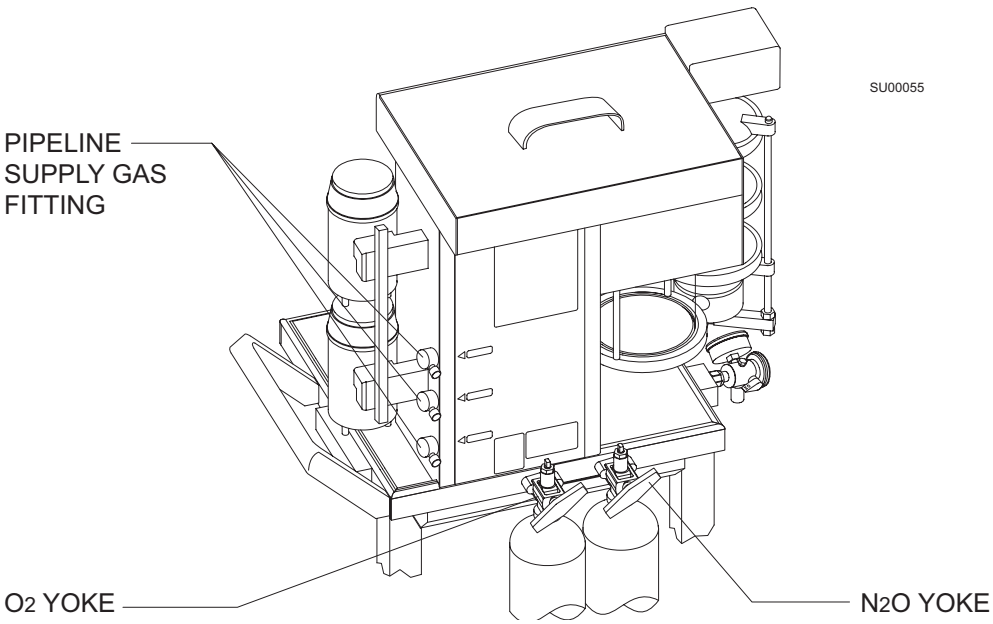
Gas Supply Connections

Section contents:

Gas Supply Connections

The gas supply connections for pipeline and gas cylinders are shown in the following illustration.



Connecting the Cylinders

The Narkomed MRI is equipped with ANSI standard pin-indexed hanger yokes for E-size aluminum gas cylinders.

WARNING: Use only nonmagnetic (aluminum) E-cylinders with this machine. Steel cylinders can cause serious injury or death if brought into an MRI scanning room.

WARNING: Oil and grease may combine explosively with oxygen or nitrous oxide. For this reason, oil and grease must never come in contact with pipelines, cylinders, cylinder valves, gauges, fittings, etc., that conduct oxygen or nitrous oxide within the machine. For further information regarding safety precautions in the use of medical gases, consult Compressed Gas Association pamphlet P-2 and appropriate sections of National Fire Protection Association Standard 99.

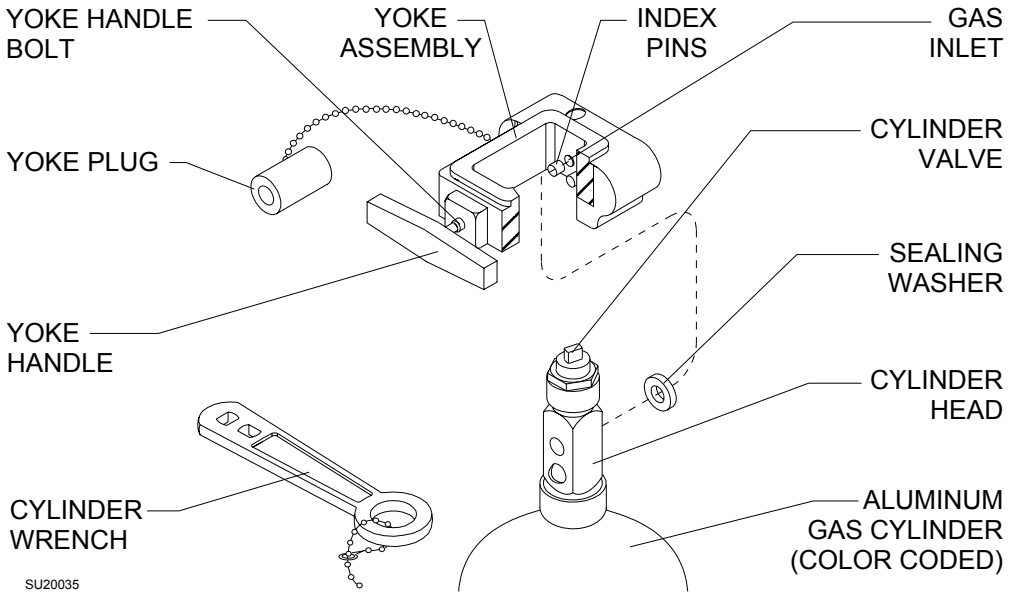
Attach cylinders as follows:

1. Place a new washer on the seat of the yoke gas inlet connection.

WARNING: Use only one cylinder washer for the yoke. Using more than one washer can cause gas leakage and compromise the pin-indexing system.

2. Verify the presence and integrity of the two index pins below the gas inlet.

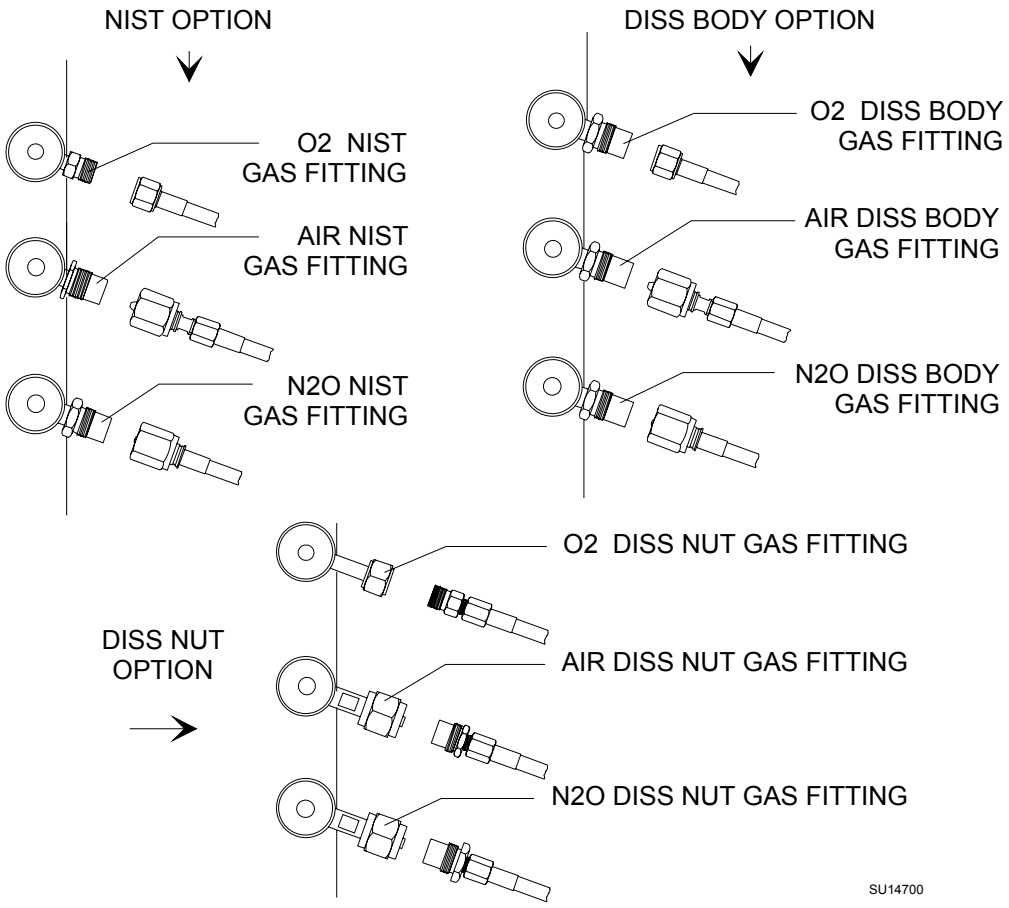
WARNING: Check cylinder yokes for the presence of two index pins each time a cylinder is attached to the machine.



3. Insert the head of a gas cylinder with matching gas into the yoke from below, so that the gas outlet and indexing holes on the cylinder head are facing the gas inlet and indexing pins on the yoke.
4. Engage the indexing holes with the index pins. Screw the yoke handle clockwise against the cylinder head, so the point of the yoke handle bolt is aligned with the countersunk recess on the back of the cylinder head.
5. Verify that the sealing washer is in place, that the index pins are engaged, and that the cylinder hangs vertically. Tighten the handle securely.
6. Perform a high pressure leak test.

Connecting the Pipelines

Pipeline connections for oxygen, nitrous oxide, and air are located on the side of the flowmeter housing. The pipeline inlets are marked with color-coded labels. Several pipeline fitting styles are illustrated, and the table below lists the gas system color coding.



GAS SYSTEM COLOR CODING			
GAS	**MARKING**	**USA**	**ISO**
Air	AIR	Yellow	Black/White Checkered
Nitrous Oxide	N_2O	Blue	Blue
Oxygen	O_2	Green	White

WARNING: Oil and grease can combine explosively with oxygen or nitrous oxide. For this reason, oil and grease must never come in contact with pipelines, cylinders, cylinder valves, gauges, fittings, etc., that conduct oxygen or nitrous oxide within the machine. For further information regarding safety precautions in the use of medical gases, consult Compressed Gas Association pamphlet P-2 and appropriate sections of National Fire Protection Association Standard 99.

Connect the pipeline supply hoses as follows:

1. Verify that the hoses have the correct gas fittings. Connect the gas fitting on each supply hose to the corresponding gas fitting on the side of the flowmeter housing. Use a wrench to tighten the hex nut.

WARNING: Both ends of each gas supply hose must be indexed for the same gas. Pipeline delivery hoses used between wall outlets and anesthesia machines have caused accidents when, during assembly, an oxygen fitting has been placed on one end of the hose and a nitrous oxide fitting on the other end.

2. Connect the other end of each supply hose to the appropriate functioning hospital pipeline outlet.
3. Check the pipeline pressure gauge on the front of the Narkomed MRI for sufficient pipeline pressure (50-55 psi).

5 Power-up and System Configuration

Section contents:

Power-Up Diagnostics Test

1. Turn the SYSTEM POWER switch to ON. The self-diagnostic screen is displayed. A typical power-up diagnostic screen is shown in the illustration below.
2. If the machine is connected to an electrical outlet, verify that the battery-in-use (AC POWER FAIL) indicator remains unlit.

WARNING: Always lock the casters after this anesthesia machine has been positioned in the MRI scanner room. Magnetic attractive forces between the magnet and the anesthesia machine may cause unintentional movement of the machine if the casters are unlocked.

WARNING: This anesthesia machine has been tested only with magnets having field strengths of up to 3.0 tesla. Moving the machine near higher strength magnets could result in machine malfunction or unmanageable attractive forces that could lead to serious injury or death.

NARKOMED MRI
COPYRIGHT 2000 DRAEGER MEDICAL, INC.
VERSION: 1.01 NM MRI
SOFTWARE ID: 90B5

DIAGNOSTIC TESTS

FIRMWARE	PASS
RAM	PASS
VIDEO	PASS
A/D CONVERTER	PASS
AUDIO	PASS
CLOCK	PASS
NON-VOLATILE MEMORY	PASS

PERIODIC CERTIFICATION DUE
FUNCTIONAL

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Testing and PMS

Refer to the PMS Procedure given in Section 6 of the latest version of the *Narkomed MRI Technical Service Manual*, P/N 4114210, or its equivalent on the Service CD-ROM, P/N 4114417.

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6.0 PMC Procedure, Narkomed MRI

The procedures in this section shall be performed in their entirety each time a component is removed, replaced, calibrated, adjusted and during all scheduled Periodic Manufacturer's Certification (PMC) visits. A PMC Checklist form, P/N 4114551, available from the Draeger Medical, Inc. Technical Service Department, shall be completed by the Technical Service Representative each time a PMC is performed. Space is also provided on the PMC checklist form to record the results of a vapor concentration test.

NOTE: Test equipment listed below with an asterisk (*) requires calibration at a maximum interval of one year. Verify the dates on test equipment calibration labels. DO NOT USE any test equipment with an expired calibration date. Notify your supervisor immediately if any equipment is found to be out of calibration.

In the space provided at the bottom of the PMC checklist form, record the Model and EL number of all calibrated test equipment used. Also record the calibration due dates.

Test Equipment Required:

*-- Multi-Meter (Fluke or Equivalent)

*-- Electrical Safety Analyzer (Biotek 501 Pro or Equivalent)

*-- Test Pressure Gauge, P/N S000063

-- Fresh Gas Outlet Volume Test Device, P/N S010158

-- Fresh Gas Leak Test Device, P/N 4113119

-- Adapter Assembly, Test Terminal, P/N 4104389

*-- Flowmeter Test Stand (Capnomed), P/N S000081

-- Breathing System Leak Test Device, P/N S010159

-- Dow Corning High Vacuum Grease, P/N S4105908

-- Tube, Corrugated, 22 mm x 12 in. long, P/N 9995112

-- Breathing Bag, 3 liter, P/N 9995330

-- Baromed Pressure Test Fixture

*-- Test Minute Volume Meter, P/N 2212300 (or Equivalent)

*-- Digital Pressure Manometer (SenSym PDM 200CD or Equivalent)

*-- Riken Gas Indicator, Model 18

-- Stop Watch

-- Test Lung (P/N 8401892)

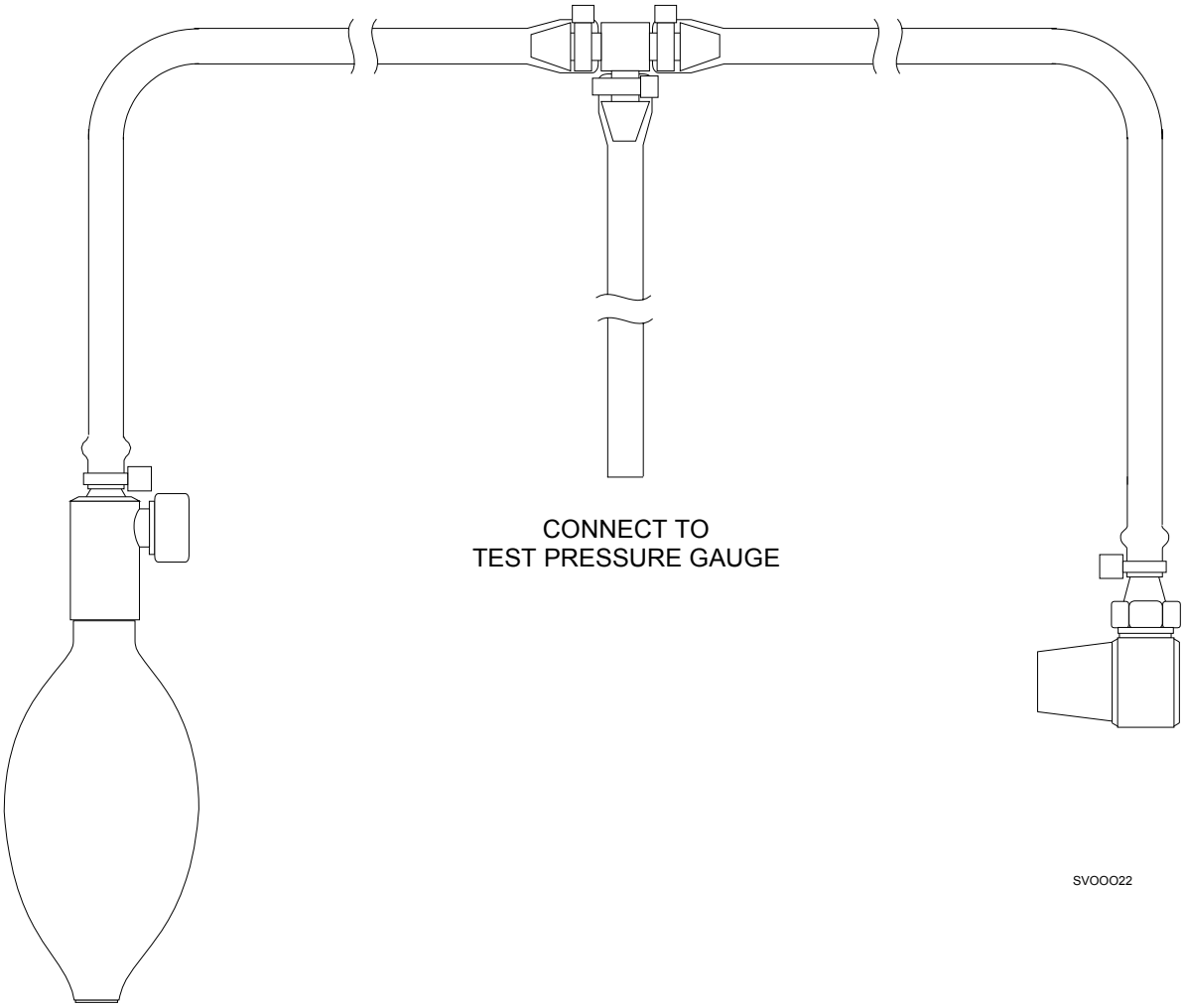
Test equipment illustrations are shown on following pages.

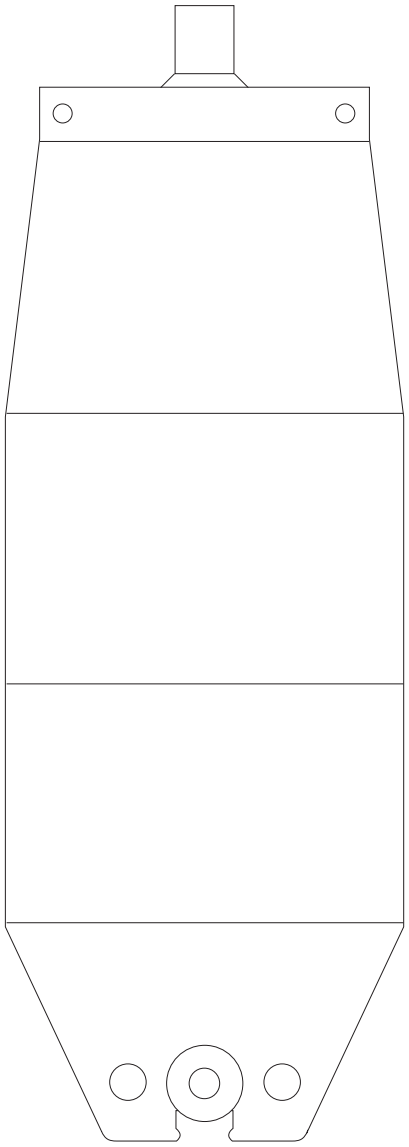
WARNING: Always lock the casters after this anesthesia machine has been positioned in the MRI scanner room. Magnetic attractive forces between the magnet and the anesthesia machine may cause unintentional movement of the anesthesia machine if the casters are unlocked.

WARNING: The power supply charger assembly must not be taken into the magnet room. Damage to the equipment, MRI system, or personal injury could result.

WARNING: The anesthesia machine must be removed from the MRI scanner room before servicing the machine. Do not enter the MRI scanner room with any tools or instruments. These items may be strongly attracted to the magnet and may cause serious injury or death when brought into an MRI scanning room.

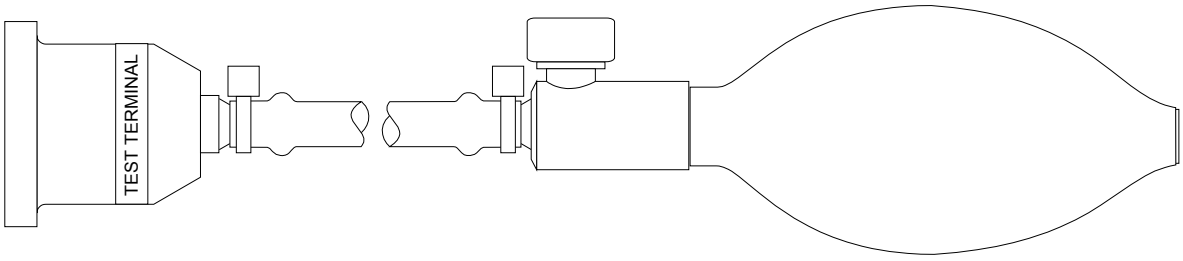
4113119
FRESH GAS LEAK TEST DEVICE



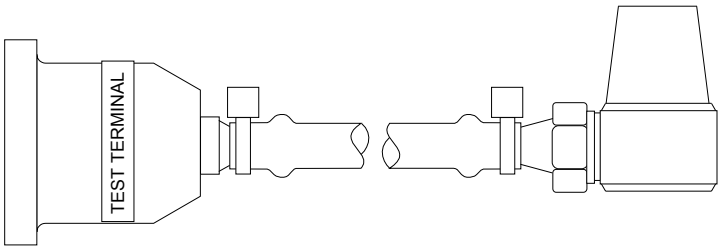


8401892
SIEMENS TEST LUNG

SV00025



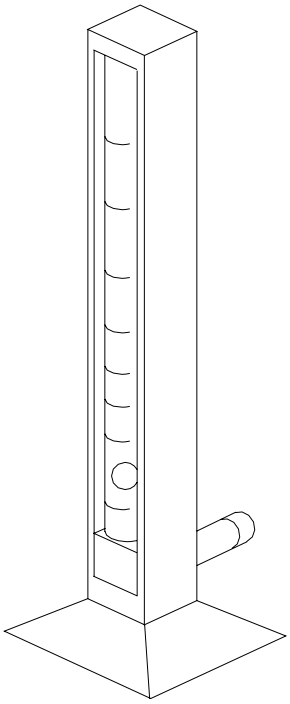
S010159
BREATHING SYSTEM LEAK TEST DEVICE



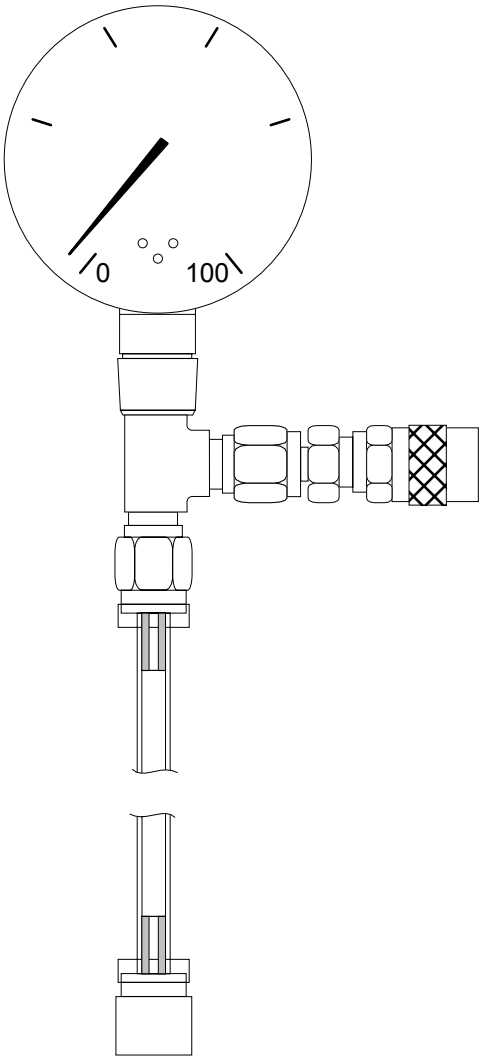
SVOOO23

S010158
FRESH GAS OUTLET VOLUME TEST DEVICE

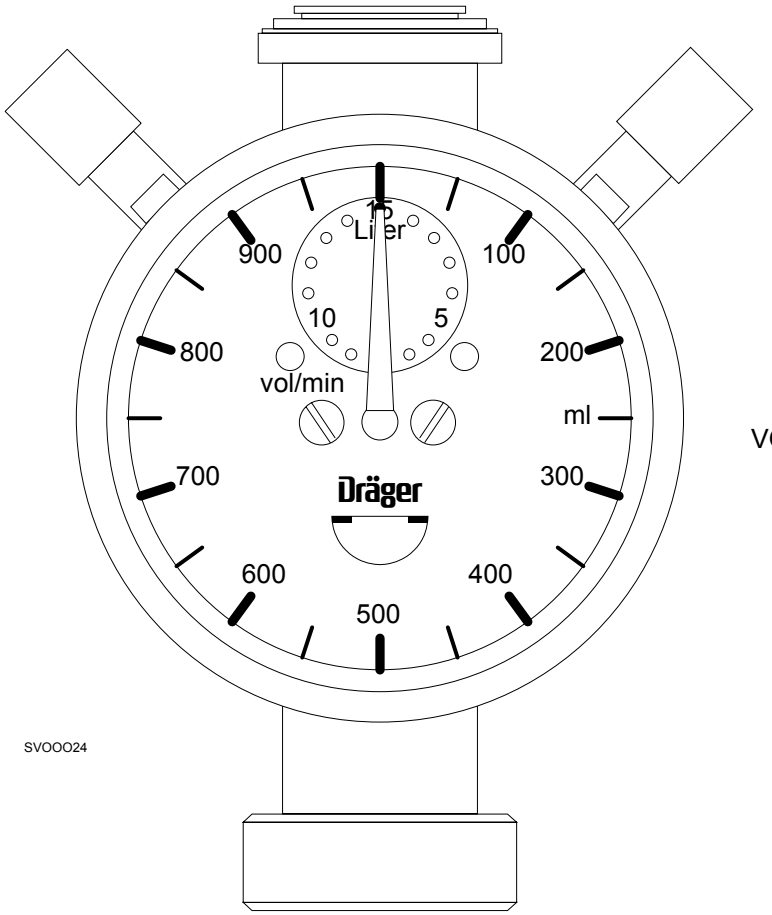
SVOOO27



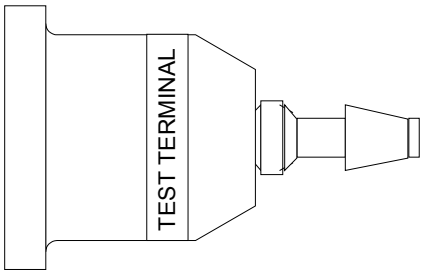
S000081
FLOW METER
TEST STAND



S000063
REGULATOR TEST
PRESSURE GAUGE



2212300
MINUTE
VOLUMETER



4104389
TEST TERMINAL
ADAPTER

Periodic Manufacturer's Certification General Instructions

The purpose of these procedures is to provide detailed instructions for performing a Periodic Manufacturer's Certification (PMC) inspection the Narkomed MRI anesthesia machine.

A PMC consists of a complete Periodic Manufacturer's Service procedure and a certification level inspection based on Draeger Medical, Inc. Recommendations and equipment performance. Additional inspections are also performed to insure proper product labeling.

Several additional documents have been created to ensure the success of this new program. Following is a brief description of the purpose of each document.

Field Service Procedure:
Periodic Manufacturer's Certification Forms - Part Number SP00175.
This procedure illustrates sample checklists with typical periodic maintenance items filled in, including vapor concentrations verification tests, parts replaced, general comments and certification levels. Also included are sample PMC labels marked to show several levels of certifications. An excerpt from DMI's *Anesthesia System Risk Analysis and Risk Reduction* is included, and also a sample of an Executive Summary to be furnished to the hospital's Risk Manager or Chief of Anesthesia.

Field Service Procedure:
DMI Recommendations Guidelines Index Anesthesia Systems - Part Number S010250.
This Guideline was created to provide an assessment of each machine's certification. It contains various comprehensive overviews of possible equipment conditions and their associated certification levels.

The first list in the Recommendation Guidelines is a reference chart for machine certification based on equipment status. The second is an abbreviated summary of all DMI Recommendations and Failure Codes including the Condition Number, Equipment Condition, Recommended Corrections, Certification Code, and Tests Affected when applicable.

There is also a matrix classified as "Failure Codes" which identifies the correct manner in which to document equipment tests that fail, or were unable to be performed due to circumstances beyond the control of the service technician performing the inspection. (Ex: Air cylinder supply is unavailable to perform Air High Pressure Leak test.) The Failure Codes section also indicates suggested resolution of the situation. Failure Code numbers begin at 34 and use the same certification levels strategy, and carry the same weight as DMI Recommendation equipment condition codes.

The final matrix is the most comprehensive index sorted by machine model and includes Equipment Condition, Certification Code, and DMI Recommendations. It also specifies any suggested upgrade path including ordering information that should be taken such as installing a Bellows with Pressure Limit Control 4109664-S01 Kit, after market modification kit to a machine not equipped with pressure limit control.

The letters A, B, C, D and the Roman Numerals I, II are used as codes in the individual matrix for each model of anesthesia machine. The letters A, B, C, and D are used in descending order to indicate the certification level of the equipment. They are as follows:

A = Certified
B = Certified with Recommendations
C = Conditionally Certified
D = No Certification

Roman Numerals I and II do not affect the certification level but rather are provided to give further instructions to the end user as follows:

I = The system in its present configuration shall only be used with a CO2 monitor incorporating an apnea warning. The operator of the system is advised to frequently scan the CO2 readings and alarm thresholds.

II = The present configuration of equipment requires that the unit operate at all times with an oxygen analyzer that includes a low oxygen warning. The operator of the system is advised to frequently scan the oxygen readings and alarm limits.

Following is an explanation of machine certification levels:

Certified- No recommendations apply to machine being inspected. (Only item number 33 - "No Recommendations" shall apply for this certification level.)

Certified with Recommendations- A numbered recommendation with a code of B applies to the machine being examined.

Conditionally Certified- A numbered recommendation with a code of BCI or BCII applies to the machine being examined.

No Certification- A numbered recommendation with a code of D applies to the machine being examined.

When multiple recommendations apply, "No Certification" would take precedence over "Conditionally Certified" and "Certified with Recommendations". "Conditionally Certified" would take precedence over "Certified with Recommendations".

For example:

A **Narkomed 3** could have recommendation number 21 and failure code 61.1 apply.
21 - No ventilator pressure limit control. Code is B.
61.1 - Enflurane agent is unavailable to test. Code is BC.
Correct certification for this machine is BC, which means CONDITIONALLY CERTIFIED WITH RECOMMENDATIONS.

A **Narkomed 4** could have recommendation numbers 14 and 21 apply.
14 - CO2/Agent monitor exhaust port is not properly connected to the waste gas scavenger. Code B.
21 - No ventilator pressure limit control. Code B.
The correct certification for this machine is B, which means “CERTIFIED WITH RECOMMENDATIONS”.

A **Narkomed 2B, 2C** or **GS** could have recommendation 30 apply.
30 - Anesthesia machine is equipped with inhalation anesthesia vaporizers without an agent analyzer in the breathing system. Code B.
The correct certification for this machine is B, which means “CERTIFIED WITH RECOMMENDATIONS”.

A **Narkomed 6000** could have no NAD recommendations or failure codes apply. The correct certification level for this machine is Code A, “CERTIFIED”.

Code D, which means “NO CERTIFICATION”, also means the machine shall not receive a Periodic Manufacturer’s Certification label. The machine shall also receive a “WARNING - This System is Not Certified” label, P/N 4114857. This label shall be placed at a prominent location on the right side of the machine after all other previous PM and “Vigilance Audit® Validation” labels have been removed.

PM Certification Procedure for Narkomed MRI Anesthesia System

1. Use the PM Certification form for Narkomed MRI Anesthesia Systems (P/N 4114551).

2. Completely fill in the header information.

3. Replace the VENTILATOR RELIEF VALVE DIAPHRAGM in accordance with SP 00075. Place a check mark and the replacement date at “VENT VALVE REPLACEMENT” line on the Periodic Manufacturer’s Certification form.

4. Check all vapor 19 and 19.1 vaporizers for correct labeling. All vaporizers must have a label stating "THE CONCENTRATION OUTPUT OF THIS VAPORIZER SHALL BE VERIFIED AFTER IT HAS BEEN ATTACHED TO THE ANESTHESIA MACHINE" (part # S010015). This label shall be attached to the rear of the vaporizer directly below the mount.

5. All Key Index Safety Systems vaporizers, (K.I.S.S.) must have a label stating "CAUTION: AFTER FILLING HAS BEEN COMPLETED, REINSERT PLUG INTO UPPER FILLER PORT AND TIGHTEN LOCKING SCREW" (part # 4112520-001). This label shall be attached to the vaporizer directly above the keyed filler. Place a check mark at "K.I.S.S. LABEL" on the PM Certification form.

6. If machine is equipped with a HALOTHANE Dräger Vapor 19 or 19.1 vaporizer, determine if vaporizer must be inspected for soil condition one. Check the serial number plate located on the rear of the vaporizer for a plus (+) preceding the serial number. A HALOTHANE vaporizer serial number not preceded with a (+) must be tested for soil in accordance with SP00073. If vaporizer does not need to be inspected, indicate so with a plus (+) next to the “Vapor Inspection (H)” line on the Vigilance Audit form. If vaporizer is soil condition 0, indicate so with “SOIL 0” written next to the “Vapor Inspection (H)” line on the Vigilance Audit form. If vaporizer is soil condition one, indicate so with “SOIL 1” writen next to the “Vapor Inspection (H)” line on the Vigilance Audit form. Place a “CAUTION DO NOT USE” label (part # 4114327) on the vaporizer, and issue a departmental alert. The TSR shall also seek permission from the equipment operator to remove the failed vaporizer from the machine and apply a replacement vaporizer or an adapter block onto the mount. All “SOIL 1” vaporizers must be removed from service for machine to receive certification.

7. Perform the vapor concentration test on all Dräger vapor vaporizers in accordance with SP00073. For every vaporizer tested, fill out a "VAPOR VAPORIZER CALIBRATION CHECK" label (part # S010016). Information on this label shall include your signature, type of agent, date tested, test results @ 1%, 2.5%, 4%, and a PASS or FAIL indication. This label shall be attached to the upper right side of the vaporizer. If vaporizer fails the concentration test, check "NO" in the "RECOMMENDED FOR USE" section on the PM Certification form.

   Place a "CAUTION DO NOT USE" label (part # 4114327) on the vaporizer, and issue a departmental alert. The TSR shall also seek permission from the equipment operator to remove the failed vaporizer from the machine and install a replacement vaporizer or an adapter block onto the mount. All nonfunctional Dräger vapor vaporizers must be removed from service for machine to receive certification.

PM Certification Procedure for Narkomed MRI Anesthesia System

8. Proceed with PM Certification procedure. If any tests fail refer to the "Failure Codes" listing in DMI Recommendations Guidelines Index (P/N S010250) to determine correct certification level starting point. Failure codes shall be documented on the "RECOMMENDATIONS / GENERAL COMMENTS" section of the PM Certification form and on the Executive Summary. If a test fails that has not been identified by the "Failure Codes" list, consult with Draeger Medical, Inc. to assess the proper certification level.

9. Based on the "EQUIPMENT CONDITION" inspect the machine for any "DMI RECOMMENDATIONS" that would apply. Use the Narkomed MRI section of the "DMI RECOMMENDATION GUIDELINES INDEX" (P/N S010250). Note all applicable DMI recommendations on the Executive Summary. NOTE: If using a carbon form, indicate the Equipment Condition number and to see reverse side under the "RECOMMENDATIONS / GENERAL COMMENTS" section of the form.

10. Determine the correct certification level of the machine based on the combined lowest common denominator of "Equipment Conditions" and "Failure Codes". If the machine is at least conditionally certified fill out the "PM CERTIFICATION" label. Check the box(s) on the validation label where appropriate. Write the month and year, (three months from date of PM Certification) next to "NEXT VISIT DUE:" If certification level is "D", machine shall not receive a "PM CERTIFICATION" label. Any machine not receiving a PM Certification label shall receive a "WARNING NOT CERTIFIED" label. This label shall be placed at a prominent location on the left side of the machine after all other previous PMC and Vigilance Audit Validation labels have been removed.

11. In the "CERTIFICATION LEVEL" section of the PM Certification form, record the last visit certification level, the current certification level and the next visit due month and year, (three months from date of PM Certification) in the spaces provided.

12. If applicable, remove the previous PM CERTIFICATION VALIDATION label and attach the new label (P/N S010006 w/phone #, or P/N S010007 w/o phone #) in a prominent location on the rear of the anesthesia machine.

13. Check the appropriate boxes on the "PM CERTIFICATION NOTICE" label, (part # S010011). If the machine is not certified, the last box of this notice label shall be marked. Attach this notice to the flow shield of the anesthesia machine.

14. Have the customer sign each PM Certification form or the Executive Summary, and review the equipment conditions and the recommendations with the customer.

15. Return top copy to Draeger Medical, Inc. Service Department, keep middle copy for service organization records, give bottom copy to customer.

6.1 Safety Testing

6.1.1 Circuit Isolation Test

6.1.1.1 Turn the System Power switch to STANDBY, remove the AC power cord from the outlet.

6.1.1.2 Set a multimeter to its highest resistance range, and carefully check for continuity between Pin 1 of the machine power connector located at the rear of the machine and any exposed unpainted surface of the machine chassis. There shall be no continuity between these points.

6.1.1.3 Reconnect the power cable to the machine power connector.

6.1.2 Protective Ground Continuity Test

NOTE: Do not plug the safety analyzer into a line isolation monitor as inaccurate readings may occur.

6.1.2.1 Plug the Biotec 501 Pro power cord into a live receptacle; place the power switch of the Biotek 501 Pro to the “1” or ON position and ensure that the keys marked GROUND, NEUTRAL and POLARITY are in the NORMAL position.

NOTE: If the corresponding red LEDs for GND, NEU and POL are not lighted, they are in the normal position.

6.1.2.2 Attach the ground lead from the red Test Lead input to the ground hole of the AC test receptacle on the Biotec 501 Pro. Select the Single Lead condition by ensuring that the SINGLE/DUAL key is not illuminated. Press the gray key marked RESIST, then press the blue key marked CAL. When the word CAL is no longer shown in the display window of the Biotec 501 Pro, you may proceed.

6.1.2.3 Remove the red lead from the ground hole of the AC test receptacle and attach the alligator clip to the free end, leaving the other end plugged into the red Test Lead input of the Biotec 501 Pro with the Single Lead and Resistance conditions still selected. Attach the alligator clip to any exposed unpainted surface of the machine chassis.

6.1.2.4 Plug the charger cord into the test receptacle of the 501 Pro. The resistance reading then shown on the Biotec 501 Pro display is the Chassis Resistance. Bend and exercise the power cord to check for intermittent readings. Record the reading on the PMC form. (≤0.1 ohm)

6.1.3 Chassis Leakage Current Test

6.1.3.1 Press the gray Leakage key. Leave all other selections from the previous test the same.

6.1.3.2 Set the white keys on the Biotec 501 Pro labeled GROUND, NEUTRAL and POLARITY for normal polarity. Record the reading on the PMC form. (0 µA)

6.1.3.3 Set the white keys for NORMAL ground, OPEN neutral and NORMAL polarity. Verify reading is zero. (0 µA)

6.1.3.4 Set the white keys for OPEN ground, NORMAL neutral and NORMAL polarity. Record the reading on the PMC form. Note: Old power supply: ≤150 µA but not zero. New power supply: ≤120 µA but not zero.

6.1.3.5 Set the white keys for NORMAL ground, NORMAL neutral and REVERSE polarity. Record the reading on the PMC form. (0 µA)

6.1.3.6 Set the white keys for NORMAL ground, OPEN neutral and REVERSE polarity. Verify reading is zero. (0 µA)

6.1.3.7 Set the white keys for OPEN ground, NORMAL neutral and REVERSE polarity. Record the reading on the PMC form. Note: Old power supply: ≤150 µA but not zero. New power supply: ≤120 µA but not zero.

6.1.3.8 Return the white keys on the Biotec 501 Pro to their Normal positions.

6.2 Self-Diagnostics: Core-M Monitor

6.2.1 Connect the pipeline supply or open the cylinders.

6.2.2 Turn the System Power switch to ON.

6.2.3 Verify that the Omicron monitor LCD display and LED lamps performs a self-diagnostic test.

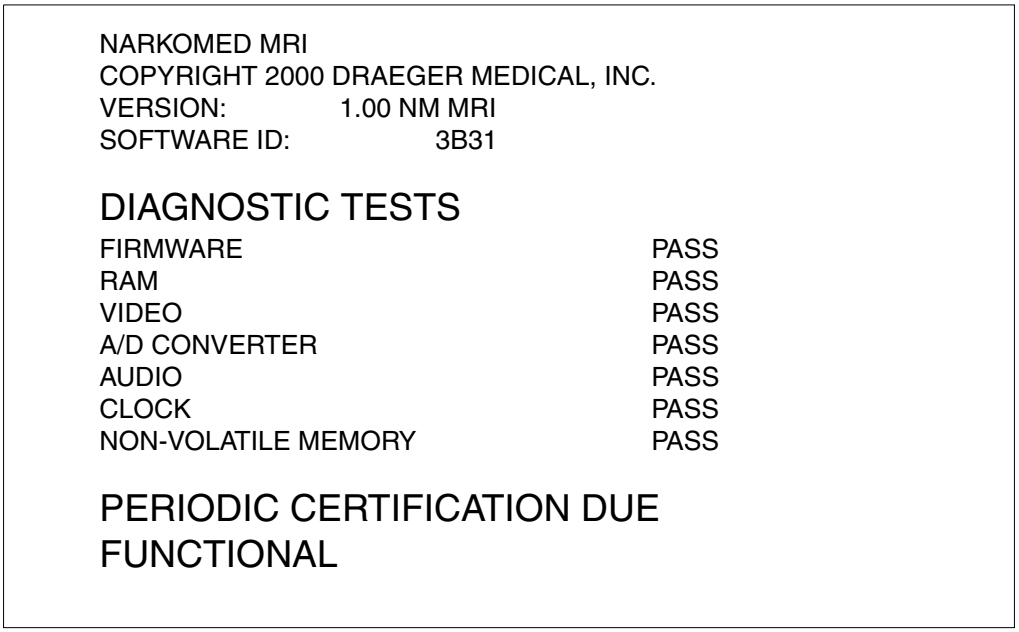
6.2.4 Verify that the green "Power" LED activates.

6.2A Self-Diagnostics: VPO Monitor

6.2.A.1 Connect the pipeline supply or open the cylinders.

6.2.A.2 Turn the System Power switch to ON.

6.2.A.3 Verify that the following is displayed:



(✓) 6.2.A.4 Record the machine software version on the header of the checklist form.

6.2B CONFIGURATION: VPO Monitor

6.2B.1 Press the CONFIG key.

6.2B.2 The CONFIGURE screen is displayed.

6.2B.3 Verify the correct Time and Date.

6.2C SERVICE DATA: VPO Monitor

6.2C.1 Press and hold the Oxygen High Limit key and the Volume Low Limit key, and then press the ▲ key.

6.2C.2 The Main Service Screen appears.

(✓) 6.2C.3 Record the Last Service Date on the PMC form.

(✓) 6.2C.4 Record the Hours Run Since Last Service on the PMC form.

(✓) 6.2C.5 Record the Total Hours Run on the PMC form.

6.2C.6 Select and enter the Service Log.

6.2C.7 Verify any pertinent information from the Service Log. Contact the Draeger Medical, Inc. Technical Service Department if necessary.

6.2C.8 Press EXIT to return to the Main Service screen.

6.2C.9 Select the SRVC Service Code.

6.2C.10 Select and enter your Technical Service Rep. I.D. number.

(✓) 6.2C.11 Press the RESET key. This resets the last service date to the current date and resets the hours run since last service to zero.

6.2C.12 Press the PMS SCHED key.

(✓) 6.2C.13 Select and enter the month of the next service due date. The internal clock of the machine limits the amount of date advance to a maximum of six months from the current service date.

6.3 Battery Circuit Test

6.3.1 Deleted

6.3.2 If needed, replace the battery as outlined in the Battery Replacement Procedure in Section 4 of this manual/

6.3.3 Is "ON" LED lighted? __ (Y)

6.3.4 With the System Power switch ON, unplug the AC power cord.

6.3.5 Is yellow "AC PWR FAIL" LED lighted as long as the power cord is unplugged? __ (Y)

6.3.6 Press and hold the "BATTERY TEST" button.

6.3.7 Is green Battery Test LED lighted as long as "BATTERY TEST" button is depressed? __ (Y)

6.3.8 Release the "BATTERY TEST" button.

6.3.9 Restore AC power to the machine.

6.3.10 Does the "AC PWR FAIL" LED extinguish? __ (Y)

6.4 High Pressure Leak Test

6.4.1 Yoke Assemblies

6.4.1.1 Turn the ventilator off.

6.4.1.2 Turn the System Power switch to STANDBY.

6.4.1.3 Disconnect the pipeline supply or close the cylinders.

6.4.1.4 Remove cylinder or yoke plug from each yoke assembly.

6.4.1.5 Do all the yoke handles adjust smoothly? ___ (Y)

6.4.1.6 Are the two (2) yoke pins installed securely in each yoke? ___ (Y)

6.4.1.7 Is there only one (1) cylinder washer on each yoke assembly? ___ (Y)

6.4.1.8 Is there a yoke plug attached to each yoke assembly? ___ (Y)

6.4.1.9 Is the proper gas I.D. label affixed to each yoke assembly? ___ (Y)

6.4.1.10 Attach a cylinder to each yoke assembly, open the cylinder valve, let the pressure stabilize, close the cylinder valve, and remove the cylinder from the yoke assembly.

6.4.1.11 Does the yoke check valve assembly prevent the escape of excessive pressure? ___ (Y)

6.4.1.12 Attach the cylinders to the yokes.

6.4.2 Oxygen High Pressure Leak Test

6.4.2.1 Disconnect the pipeline supplies.

6.4.2.2 Turn the System Power switch to STANDBY.

6.4.2.3 Open the oxygen cylinder valve.

6.4.2.4 Let the pressure stabilize.

6.4.2.5 Close the oxygen cylinder valve and remove the cylinder.

6.4.2.6 Observe the oxygen cylinder pressure gauge.

6.4.2.7 After two (2) minutes, what is the pressure loss? ___ PSI (<50)

6.4.2.8 Attach the cylinder.

6.4.3 Nitrous Oxide High Pressure Leak Test

6.4.3.1 Turn the System Power switch to ON.

6.4.3.2 Open one (1) oxygen cylinder valve and one (1) nitrous oxide cylinder valve.

6.4.3.3 Adjust the oxygen flow to 8 l/min.

6.4.3.4 Let the pressure stabilize.

6.4.3.5 Close the nitrous oxide cylinder valve and remove the cylinder.

6.4.3.6 Observe the nitrous oxide cylinder pressure gauge.

6.4.3.7 After two (2) minutes, what is the pressure loss? ___ PSI (<50)

6.4.3.8 Attach the cylinder.

6.4.3.9 Close the oxygen flow control valve.

6.5 High Pressure Regulator Test

6.5.1 Disconnect all pipeline hoses and set the System Power switch to ON.

6.5.2 Close all cylinder valves except the O_2 valve.

6.5.3 Set the oxygen flow to 5 liters per min.

6.5.4 Open the other gas flow control valves to drain pressure from the system.

6.5.5 Close the O_2 cylinder valve, and close the flow control valves. Press the O_2 Flush valve to drain oxygen pressure from the system.

6.5.6 Set the System Power switch to STANDBY.

6.5.7 Remove the table top from the machine.

6.5.8 Locate the TEE fitting in the ¼ in. diameter O_2 regulator output line, and remove the plug from the TEE fitting.

6.5.9 Connect a dedicated O_2 test gauge to the TEE fitting.

NOTE: Two test gauges are required to avoid contamination of the O_2 circuit from the other gases: a dedicated test gauge for O_2, and a second test gauge for the other gases.

6.5.10 Open the O_2 cylinder valve and set the System Power switch to ON.

6.5.11 Set the oxygen flow to 4 liters per min.

6.5.12 On the test gauge, what is the regulator output pressure? ___PSI (42-48)

NOTE: Leave the dedicated O_2 test gauge connected for later use in the Oxygen Supply Pressure Alarm Test.

6.5.13 Set the System Power switch to STANDBY.

6.5.14 For the other pressure regulators, locate their corresponding TEE fittings in the ¼ in. diameter regulator output line, and remove the plug from the TEE fitting (one at a time).

6.5.15 Connect the second test gauge to the TEE fitting.

6.5.16 Open the corresponding cylinder valve and set the System Power switch to ON.

6.5.17 Set the corresponding flow to 4 l/min. (900 ml/min. for CO_2).

6.5.18 On the second test gauge, what is the regulator output pressure? ___ PSI (42 - 48), (27 - 33 for CO_2)

6.5.19 Depressurize the gas circuit.

6.5.20 Remove the test gauge and replace the plug in the TEE fitting.

6.5.21 Repeat the test for all other gases.

6.6 Gauges

6.6.1 Cylinder Gauges

6.6.1.1 Are the pressure gauges correct for the gases indicated by the flowmeters? ___ (Y)

6.6.1.2 Is the gauge closest to the table top for cylinder supply pressure? ___ (Y)

6.6.1.3 Bleed all pressure from the cylinder circuit.

6.6.1.4 Are the cylinder gauges at zero (0) PSI? ___ (Y)

6.6.1.5 Open the cylinder valves.

6.6.1.6 Do the cylinder pressure gauges respond properly? ___ (Y)

6.6.1.7 Are the gauges labeled "Non-Magnetic"? ___ (Y)

6.6.2 Pipeline Gauges

6.6.2.1 Are the gauges below the flowmeters for pipeline supply pressure? ___ (Y)

6.6.2.2 Are the pipeline pressure gauges at zero (0) PSI? ___ (Y)

6.6.2.3 Connect the pipeline supply.

6.6.2.4 Do the pipeline pressure gauges respond properly? ___ (Y)

6.6.2.5 Are the correct gas identification labels affixed at each of the pipeline inlets? ___ (Y)

6.6.2.6 Does the back panel identify each of the pipeline inlets properly? ___ (Y)

6.6.2.7 Are the gauges labeled "Non-Magnetic"? ___ (Y)

6.7 Oxygen Supply Failure Protection

6.7.1 Nitrous Oxide O.F.P. Device

6.7.1.1 Disconnect the pipeline supplies.

6.7.1.2 Open and close the oxygen cylinder valve.

6.7.1.3 Open the nitrous oxide cylinder valve.

6.7.1.4 Set the O_2 and N_2O flows to 4 l/min.

6.7.1.5 Does the flow of nitrous oxide cease when the oxygen pressure is depleted? ___ (Y)

6.7.1.6 Connect the O_2 pipeline supply.

6.7.1.7 Close the nitrous oxide cylinder valve and bleed the pressure from the circuit.

6.7.1.8 Connect the N_2O pipeline supply.

6.7.1.9 Disconnect the O_2 pipeline supply.

6.7.1.10 Does the flow of nitrous oxide cease when the oxygen pressure is depleted? ___ (Y)

6.7.1.11 Close the nitrous oxide flow control valve.

6.7.2 Air O.F.P. Device - If Applicable

6.7.2.1 Connect the air pipeline supply.

6.7.2.2 Open one (1) oxygen cylinder valve.

6.7.2.3 Set the air flow to 4 l/min; set the oxygen flow to 4 l/min.

6.7.2.4 Close the oxygen cylinder valve.

6.7.2.5 Does the flow of air cease when the oxygen pressure is depleted? ___ (Y)

6.7.2.6 Close the air flow control valve.

6.7.3 Oxygen Supply Pressure Alarm

6.7.3.1 If not already connected, connect a dedicated O_2 test gauge to the TEE fitting in the O_2 regulator output line.

6.7.3.2 Open and close an oxygen cylinder.

6.7.3.3 Set the oxygen flow to 2 l/min.

6.7.3.4 What is the pressure on the dedicated O_2 test gauge when the "O2 SUPPLY PRESSURE" LED turns on? ___ PSI (34-40)

6.7.3.5 Close the flow control valve.

6.7.3.6 Remove the test gauge from the TEE fitting in the O_2 regulator output line and replace the plug.

6.8 Flowmeter Test

6.8.1 Oxygen Flowmeter Test

6.8.1.1 Open the O_2 cylinder valve.

6.8.1.2 Is it possible to adjust the flow of oxygen over the full range of the flowmeters? ___ (Y)

6.8.1.3 Close the O_2 cylinder valve and bleed the pressure.

6.8.1.4 Connect the O_2 pipeline supply.

6.8.1.5 Is the correct flow control knob and label attached to the oxygen flow control valve? ___ (Y)

6.8.1.6 Close the oxygen flow control valve.

6.8.1.7 What is the minimum flow of oxygen? ___ ml (100-200) ml/min

6.8.2 Nitrous Oxide Flowmeter Test

6.8.2.1 Set the oxygen flow to 4 l/min.

6.8.2.2 Open the nitrous oxide cylinder valve.

6.8.2.3 Is it possible to adjust the flow of nitrous oxide over the full range of the flowmeter? ___ (Y)

6.8.2.4 Close the nitrous oxide cylinder valve and bleed the pressure.

6.8.2.5 Connect the N_2O pipeline supply.

6.8.2.6 Is the correct flow control knob and label attached to the N_2O flow control valve? ___ (Y)

6.8.2.7 Close the oxygen and nitrous oxide flow control valves.

6.8.3 Air Flowmeter Test

6.8.3.1 Connect the Air pipeline supply (if applicable) and verify operation of the air flowmeter.

6.8.3.2 Close the air flow control valve and disconnect the Air pipeline supply.

6.8.3.3 Is the correct flow control knob and label attached to the air flow control valve? ___ (Y)

6.8.4 Auxiliary Oxygen Flowmeter Test - If Applicable

6.8.4.1 Close the flowmeter flow control valve.

6.8.4.2 Connect a cm H_2O pressure manometer to the outlet.

6.8.4.3 Is there an increase in pressure? ___ (N)

6.8.4.4 Remove the gauge and test fixture.

6.8.4.5 Is it possible to adjust the flow over the full range of the flowmeter? ___ (Y)

6.8.4.6 Set the flow rate to 5 l/min.

6.8.4.7 Hold the sensor from a calibrated O_2Med at the flowmeter outlet.

6.8.4.8 After 90 seconds, what is the oxygen concentration? ___ % (97-100)

6.8.4.9 Remove the O_2Med sensor.

6.8.4.10 Close the flowmeter flow control valve.

6.9 Freshgas Leak Test

6.9.1 Turn the System Power switch to STANDBY.

6.9.2 Remove the 15 mm connector from the FRESHGAS OUTLET.

6.9.3 Is the common gas outlet assembly in good condition? ___ (Y)

6.9.4 Connect a digital pressure manometer and Fresh Gas Leak Test Device to the freshgas outlet.

6.9.5 Apply 50 cm H_2O of pressure to the system.

6.9.6 After thirty (30) seconds, what is the pressure on the manometer? ___ (>40 cm H_2O)

6.9.7 Turn on the left mounted vaporizer to the first graduated marking.

6.9.8 Apply 50 cm H_2O of pressure to the system.

6.9.9 After thirty (30) seconds, what is the pressure on the manometer? ___ (>40 cm H_2O)

6.9.10 Turn off the vaporizer.

6.9.11 Remove the test equipment from the Fresh Gas Outlet.

6.9.12 Turn the System Power switch to ON.

6.9.13 Open the O_2 flow control valve to 5 l/min., purge the system for 5 seconds, then close the O_2 flow control valve.

6.9.14 Turn the System Power switch to STANDBY.

6.9.15 Connect the 15 mm connector from the breathing system.

6.9.16 Is the FRESHGAS OUTLET label on the freshgas outlet? ___ (Y)

6.10 Absorber System

6.10.1 Absorber System Inspection

6.10.1.1 Remove the inspiratory and the expiratory valve domes.

6.10.1.2 Is there a broken or bent pin on the valve assembly?
Inspiratory ___ (N) Expiratory ___ (N)

6.10.1.3 Is there a broken pin on the valve domes?
Inspiratory ___ (N) Expiratory ___ (N)

6.10.1.4 Is the valve disc in good condition?
Inspiratory ___ (Y) Expiratory ___ (Y)

6.10.1.5 Are the valve dome washers in good condition? ___ (Y)

6.10.1.6 Reinstall the inspiratory and expiratory valve domes.

6.10.1.6A Remove the ultrasonic flow sensor connector hose - if applicable.

6.10.1.6B Is the connector hose, connector, and O-ring in good condition? ___ (Y) - if applicable.

6.10.1.6C Remove the ultrasonic flow sensor from the mounting bracket - if applicable.

6.10.1.6D Remove the flow housing/transducer assembly from the electronics housing - if applicable.

6.10.1.6E Remove both transducers from the flow housing; examine each O-ring and condition of all components, then reassemble - if applicable.

6.10.1.7 Remove the inspiratory and expiratory valve assemblies.

6.10.1.8 Are the two (2) washers in good condition? ___ (Y)

6.10.1.9 Reinstall the inspiratory valve.

6.10.1.10A Reinstall the expiratory valve and the connector hose between the expiratory valve and the ultrasonic flow sensor - if applicable.

6.10.1.10 Are the two (2) spring clips on the absorber rods?___ (Y)

6.10.1.11 Inspect the following: canisters and gaskets, dust cup and O-ring, condition of soda lime.

6.10.1.12 Are the canisters and dust cup in good condition?___ (Y)

6.10.1.13 Is the cm H_2O gauge at zero (0)? ___ (Y)

6.10.1.14 Verify that the gauge is labeled "Non-Magnetic."

6.10.1.15 Remove the O_2Med sensor plug from the inspiratory valve dome adapter and examine the two O-rings at the bottom of the plug.

6.10.1.16 Examine the two O-rings at the bottom of the sensor.

6.10.1.17 Reinstall the O_2Med sensor plug into the inspiratory valve dome adapter.

6.10.2 Absorber System Leak Test

6.10.2.1 Turn the System Power switch to STANDBY.

6.10.2.2 Close all flow control valves.

6.10.2.3 Short-circuit the inspiratory and expiratory valves with a 12-inch hose.

6.10.2.4 Attach a test terminal with a cuff inflation bulb (P/N S01059) to the bag mount.

6.10.2.5 Set the Man/Auto selector valve to BAG.

6.10.2.6 Close the APL valve.

6.10.2.7 Apply 50 cm H_2O pressure to the absorber system.

6.10.2.8 After 30 seconds, what is the pressure in the absorber system? ___ cm H_2O ($\geq$30)

6.10.3 APL Valve Test

6.10.3.1 Open the APL valve to its stop.

6.10.3.2 Turn the SYSTEM POWER switch to ON.

6.10.3.3 Set the oxygen flow to 8 l/min.

6.10.3.4 What is the pressure on the absorber pressure gauge? ___ cm H_2O ($\leq$3)

6.10.3.5 Close the oxygen flow control valve, turn the System Power switch to STANDBY, and remove the test terminal from the bag mount.

6.10.4 Absorber Flow Direction and Leak Test

6.10.4.1 Expiration Valve Leak Test

6.10.4.1.1 Close the APL valve.

6.10.4.1.2 Connect a 22mm hose between the inspiration valve and the bag mount.

6.10.4.1.3 Connect a test terminal to the expiration valve or expiratory hose terminal on the ultrasonic flow sensor, it applicable.

6.10.4.1.4 Connect a Capnomed flowmeter to the test terminal.

6.10.4.1.5 Turn the System Power switch to ON, turn up the oxygen flow until the system pressurizes to 30 cmH_2O.

6.10.4.1.6 Verify that the value indicated on the flowmeter is _60ml/min.

6.10.4.1.7 Remove all test equipment, and turn the System Power switch to STANDBY.

6.10.4.2 Inspiratory valve leak test

6.10.4.2.1 Connect a test terminal to the inspiratory valve.

6.10.4.2.2 Connect a tee adapter and calibrated pressure meter to the test terminal.

6.10.4.2.3 Connect a pressure bulb to the open port of the tee adapter.

6.10.4.2.4 Connect another test terminal to the bag connector.

6.10.4.2.5 Connect a Capnomed flowmeter to the test terminal on the bag mount.

6.10.4.2.6 Pressurize the system to 30 cmH_2O.

6.10.4.2.7 Verify that the flow meter indicates _60 ml/min.

6.10.4.2.8 Remove all test equipment.

6.10.4.2.9 Open the APL valve.

6.10.4.3 Flow Direction Test

6.10.4.3.1 Attach a breathing circuit with a 3-liter bag at the Y-piece to the inspiration valve and expiration valves or the expiratory hose terminal on the ultrasonic flow sensor, if applicable.

6.10.4.3.2 Attach a 3-liter bag to the swivel bag mount.

6.10.4.3.3 Turn the System Power switch to ON.

6.10.4.3.4 Set the O_2 flow to 4 l/min.

6.10.4.3.5 Inflate the simulated lung by briefly using the O_2 Flush.

6.10.4.3.6 Partially close the APL valve.

6.10.4.3.7 Squeeze the breathing bag attached to the bag mount at a rate of approximately 10 BPM. Readjust the APL valve if required to properly ventilate the simulated lung.

6.10.4.3.8 Observe the operation of each unidirectional valve disc at eye level and make sure the inspiratory valve disc raises only during the inspiration phase, and the expiratory valve raises only during the exhalation phase. Watch the valves until satisfied that both valves operate correctly, and move freely without sticking.

6.10.4.3.9 Open the APL valve.

6.10A Bain Circuit Adapter - if applicble

6.10A.1 Close the APL valve by turning the knob fully clockwise.

6.10A.2 Insert the O_2 sensor plug into the O_2 sensor inlet on the Bain Circuit.

6.10A.3 Attach a test terminal with a cuff inflation bulb (P/N S010159) to the Breathing Bag port on the Bain Circuit.

6.10A.4 Attach a cmH_2O digital pressure meter to the female quick connect connection on the Bain Circuit.

6.10A.5 Occlude the expiration port on the Bain Circuit.

6.10A.6 Apply 50cmH_2O to the Bain Circuit via test terminal and inflation bulb.

(✓) 6.10A.7 After 30 seconds, what is the pressure on the cmH_2O digital pressure meter? (45 to 50 cmH_2O)

6.10A.8 Verify that the pressure indicated on the cmH_2O gauge is within 3 cmH_2O of the digital pressure meter reading.

6.10A.9 Open the APL valve by turning the knob fully counter-clockwise.

6.10A.10 Connect a test hose from the fresh gas outlet to the Expiration port of the Bain Circuit.

6.10A.11 Set the O_2 flow to 10 L/min.

(✓) 6.10A.12 What is the pressure on the cmH_2O digital pressure meter? (_ 3 cmH_2O)

6.10A.13 Verify that the pressure indicated on the cmH_2O gauge is within 3 cmH_2O of the digital pressure meter reading.

6.10A.14 Remove the test terminal and inflation bulb from the Breathing Bag port.

6.10A.15 Return all controls to their original positions.

6.10B Vapor Exclusion System (if applicable)

6.10B.1 Set all vapors to (0).

6.10B.2 Adjust the handwheel on the upper vapor (viewed from the front of the machine) to any concentration above zero (0).

6.10B.3 Is it possible to adjust the lower vapor? ___ (N)

6.10B.4 Set the handwheel on the upper vapor to zero (0).

6.10B.5 Adjust the handwheel on the lower vapor to any concentration above zero (0).

6.10B.6 Is it possible to adjust the upper vapor? ___ (N)

6.10B.7 Return the handwheel on the lower vapor to zero (0).

6.11 Flow and Pressure Calibration: Core-M Monitor

NOTE: A "FLOW CAL" message must appear on the display prior to continuing with testing. This message appears after the 15 minute warm up period has completed.

6.11.1 Deleted

6.11.2 Verify that a flow sensor is attached to the volume sensor pilot line.

6.11.3 Remove the flow sensor from the absorber system.

6.11.4 Press the "FLOW CAL" key with the flow sensor exposed to room atmosphere.

6.11.5 Verify that the flow calibration has successfully completed.

6.11A Flow and Pressure Calibration: VPO Monitor

6.11A.1 To bring up the Oxygen Monitor Service Screen, press the Mon Cal key.

6.11A.2 Remove the oxygen sensor from the valve dome adapter, and remove the oxygen sensor capsule from the oxygen sensor housing.

(✓) 6.11A.3 When the CURRENT CELL A and CURRENT CELL B readings have stabilized, press the ZERO key and verify that the new offset values are stored.

NOTE: The higher the offset, the higher the calculated oxygen concentration appears at high concentrations.

6.11A.4 Put the oxygen sensor capsule into the oxygen sensor housing.

6.11A.5 Press the PRESS MON key.

6.11A.6 Disconnect the Baromed breathing pressure sensor line from the absorber and expose it to air.

6.11A.7 Let the Current Pressure Value stabilize and press the ZERO key to store the value.

6.11A.8 Connect a test fixture and a calibrated digital pressure manometer to the breathing pressure sensor line.

6.11A.9 Pressurize the circuit to 50 cm H_2O and allow the Current Value to stabilize.

(✓) 6.11A.10 Press the SPAN key and verify that the new span values are stored.

6.11A.11 Release the pressure, disconnect the manometer and test fixture, and reconnect the breathing pressure sensor line to the absorber.

6.11A.12 Press EXIT to return to the Main Service screen.

6.11A.13 Press EXIT to return to normal operation.

6.12 Oxygen Cal and Alarm Test: Core-M Monitor

6.12.1 Expose the O_2 sensor to room air.

6.12.2 Press the "O_2" key on the monitor.

6.12.3 Press the "21% O_2 CAL" key for 3 seconds.

6.12.4 What is the oxygen concentration? ___% (20-22)

6.12.5 Set the oxygen low alarm limit to 30, and pres the O_2 monitor key.

6.12.6 Verify that the "O_2 LO LMT" and "Hi Alert" audible and visual alarms activate within 5 seconds.

6.12.7 Press the Alarm Silence key and verify that the audible alarm stops.

6.12.8 Set the oxygen low alarm limit to 18.

6.12.9 Place the sensor into the valve dome, set the oxygen flow to 4 l/min., set the Man/Auto selector to BAG, close the APL valve, attach a 12 inch hose to the inspiratory valve and occlude the bag mount. Press the O_2 Flush button for 5 seconds.

6.12.10 Allow a few moments for the sensor to purge, and press the "100% CAL" key.

6.12.11 What is the oxygen concentration? ___% (97 to 100)

6.12.12 Set the oxygen high alarm limit below 100, and press the O_2 monitor key.

6.12.13 Verify that the "O_2 HI LMT" and "Low Alert" audible and visual alarms activate within 5 seconds.

6.12.14 Set the oxygen high limit to 100 (blank equals 100) and restore all controls to their original positions.

6.12A O2 MED: VPO Monitor

6.12A.1 Disconnect the oxygen sensor cable from the Oxygen Sensor interface.

6.12A.2 The following message shall appear on the display: O2 SENS DISC.

6.12A.3 Reconnect the O_2 Med sensor.

6.12A.4 The following message shall appear on the display: CAL O2 SENSOR.

6.12A.5 Press the Cal key.

NOTE: Make sure that the sensor has stabilized in ambient air for several minutes.

(✓) 6.12A.6 After calibration is completed, what is the oxygen concentration? ___ % (21)

6.12A.7 This step intentionally left blank.

6.12A.8 The warning INSP O2 LOW shall appear on the display and the warning heading shall be flashing. There shall be a continuous audible alarm.

6.12A.9 What is the low oxygen alarm default? ___ % (30)

6.12A.10 This step intentionally left blank.

6.12A.11 Select the OXYGEN LOW alarm limit. Does a box appear around the low alarm limit? ___ (Y)

6.12A.12 Verify that the low alarm limit has a range from 18 to 99%.

6.12A.13 Place the oxygen sensor into the inspiratory valve dome adapter, set the Man/Auto selector BAG, close the APL valve. Attach a 12-inch hose to the inspiratory valve and occlude the bag mount.

6.12A.14 Set the oxygen flow to 4 l/min.

6.12A.15 Set the low limit to 18, and verify that the INSP O2 LOW message has cleared.

6.12A.16 Select the OXYGEN HIGH alarm limit. Does a box appear around the high alarm limit? ___ (Y)

6.12A.17 What is the high oxygen alarm default? ___ % (100)

6.12A.18 Verify that the high alarm limit has a range from 100 to 19%.

6.12A.19 Set the high alarm limit to 95.

6.12A.20 The message INSP O2 HIGH shall appear as an Advisory.

6.12A.21 Return the high alarm limit to 100.

6.12A.22 The INSP O2 HIGH message shall disappear.

(✓) 6.12A.23 Within 3 minutes, what is the oxygen concentration? ___ % (97-100)

6.13 Pressure Accuracy Test: Core-M Monitor

6.13.1 Interconnect the inspiratory and expiratory valves with a 12 inch hose with 22 mm ends (P/N 9995112).

6.13.2 Connect a pressure meter to the breathing pressure pilot line fitting on the absorber.

6.13.3 Attach a test terminal (P/N 4104389) with a cuff inflation bulb and hose assembly (P/N 4109398) to the bag mount.

6.13.4 Set the Man/Auto selector valve to BAG, and close the APL valve.

6.13.5 Press the PRES key on the monitor.

6.13.6 Pressurize the system to 30 cmH_2O on the pressure meter.

6.13.7 Depressurize the absorber system and verify that the monitor display indicates 28 to 32 cmH_2O.

6.13.8 Set the Pressure Hi Limit to 50, and press the PRES key on the monitor.

6.13.9 Pressurize the system above 50 cmH_2O on the pressure meter and verify that the pressure "Hi Limit" and "Hi Alert" audible and visual alarms activate within 5 seconds.

6.13.10 Remove the pressure meter from the absorber system, and disable all alarms by pressing the APNEA STBY key.

6.13A BAROMED: VPO Monitor

6.13A.1 Disconnect the breathing pressure sensor line from the absorber.

6.13A.2 Connect a test pressure gauge and syringe to the breathing pressure sensor line.

6.13A.3 Select the THRESHOLD PRES alarm limit. Does a number appear to the left of the threshold line on the waveform? ___ (Y).

6.13A.4 What is the threshold alarm default? ___ cm H_2O (12)

6.13A.5 Verify that the threshold alarm limit has a range from 5 to 30 cm H_2O.

6.13A.6 Adjust the threshold to 10 cm H2O.

6.13A.7 Select the PRESSURE HIGH alarm limit. Does a box shall appear around the High Pressure Alarm Limit? ___ (Y)

6.13A.8 What is the high alarm limit default? ___ cm H_2O (50)

6.13A.9 Verify that the high alarm limit has a range from 30 to 120 cm H_2O.

6.13A.10 Set the high alarm limit to 65 cm H_2O, and exit from the set up menu.

6.13A.11 Increase the pressure to 25 cm H_2O, then decrease the pressure to 20 cm H_2O. (You must perform this step within 10 seconds, otherwise a continuing pressure condition will prevail and will prevent completionof the test.)

6.13A.12 Does the THRESHOLD LOW message appear in the Advisory column? ___ (Y)

6.13A.13 Set the Man/Auto valve to AUTO, and turn the ventilator ON.

6.13A.14 Bleed the pressure and start a stopwatch.

NOTE:Apnea Pressure alarm times are valid only with ventilator ON.

(✓) 6.13A.15 What is the time when APNEA-PRESSURE appears in the Caution column? ___ sec (13-17)

(✓) 6.13A.16 What is the time when the APNEA-PRESSURE appears in the Warning column? ___ sec (26-34)

6.13A.17 After the APNEA-PRESSURE alarm is displayed as a Warning, slowly increase the test pressure.

(✓) 6.13A.18 At what pressure does the APNEA-PRESSURE alarm deactivate? ___ cm H_2O (7-13)

6.13A.19 Adjust the threshold to 18 cm H_2O.

6.13A.20 Increase the pressure to 20 cm H_2O, maintain the pressure, and start a stopwatch.

(✓) 6.13A.21 What is the time when CONTINUOUS PRES appears as a Warning? ___ sec (12-18)

(✓) 6.13A.22 Decreasing the pressure slowly, what is the pressure at which the CONTINUOUS PRES alarm deactivates? ___ cm H_2O (15-21)

6.13A.23 Slowly increase the pressure.

(✓) 6.13A.24 At what pressure does the VENT PRESSURE HI alarm activate? ___ cm H_2O (62-68)

6.13A.25 Bleed the pressure.

6.13A.26 Slowly create a sub-atmospheric pressure.

(✓) 6.13A.27 At what pressure does the SUB ATM PRESSURE alarm activate? ___ cm H_2O (-7 to -13)

6.13A.28 Disconnect the test gauge and syringe; reconnect the breathing pressure sensor line to the absorber.

6.13A.29 Does the SUB ATM PRESSURE alarm deactivate? ___(Y)

6.13A.30 Press the Breathing Pressure OFF key.

6.13A.31 Verify that the APNEA ALARM cannot be selected to OFF when the ventilator switch is ON.

6.14 Apnea and Volume Alarm Test: Core-M Monitor

6.14.1 Attach a patient circuit with a 3L breathing bag to the absorber system.

6.14.2 Insert a test minute volumeter between the flow sensor and the expiratory valve.

6.14.3 Set the Man/Auto selector to AUTO.

6.14.4 Set the ventilator FREQUENCY to 10 BPM.

6.14.5 Set the I:E RATIO to 1:2.

6.14.6 Set the Tidal Volume to 1000 ml.

6.14.7 Adjust the O_2 flow to 500 ml/min.

6.14.8 Inflate the bellows by momentarily pressing the O_2 Flush button.

6.14.9 Turn the ventilator ON and allow the ventilator to cycle.

6.14.10 Turn the ventilator OFF and start a timer.

6.14.11 What is the time when the "APNEA VOL" and "Mid Alert" audible and visual alarms activate? ___sec (13 to 17)

6.14.12 What is the time when the "APNEA VOL" and "Hi Alert" audible and visual alarms activate? ___sec (26 to 34)

6.14.13 Turn the ventilator ON.

6.14.14 Does the "APNEA VOL" alarm deactivate? (Y)

6.14.15 Press the MIN VOL key and set the minute volume low limit above the current displayed value.

6.14.16 Press the MIN VOL key and verify that the "MINUT LOW" and "Low Alert" audible and visual alarms activate within 13 to 17 seconds.

6.14.17 Adjust the MIN VOL LO limit to the original setting.

6.14.18 Adjust the MIN VOL HI limit below the current displayed value.

6.14.19 Press the MIN VOL key and verify that the "MINUT HI" and "Mid Alert" audible and visual alarms activate within 13 to 17 seconds.

6.14.20 Adjust the MIN VOL HI limit to the original setting.

6.14.21 Are the displayed minute volumes on the monitor and test volumeter within 15% of each other? (Y)

6.14.22 Press the TIDAL VOL key and set the tidal volume low limit above the current displayed value.

6.14.23 Press the TIDAL VOL key and verify that the "TIDAL LOW" and "LOW ALERT" audible and visual alarms activate within 5 seconds.

6.14.24 Adjust the tidal volume low limit to the original position.

6.14.25 Press the TIDAL VOL key and set the tidal volume high limit below the current displayed value.

6.14.26 Press the TIDAL VOL key and verify that the "TIDAL HI" and "HI ALERT" audible and visual alarms activate within 5 seconds.

6.14.27 Adjust the tidal volume high limit to the original position.

6.14.28 Are the displayed tidal volumes on the monitor and test volumeter within 15% of each other? (Y)

6.14.29 Press the RR key and verify that the monitor displays a respiratory rate of 9 to 11 BPM.

6.14.30 Adjust the RR HI limit below the current displayed respiratory rate.

6.14.31 Press the RR key and verify that the "RATE ALRM" and "Hi Alert" audible and visual alarms activate within 13 to 17 seconds.

6.14.32 Adjust the RR HI limit to 60 BPM.

6.14.33 Remove the test volumeter.

6.14A Ultrasonic Flow Sensor: VPO Monitor

6.14A.1 Press the Breathing Volume LOW LIMIT key. Does a box appear around the Minute Volume Alarm Limit? ___(Y)

6.14A.2 What is the low minute volume alarm default? ___ (1.0)

6.14A.3 Verify that the minute volume has a low alarm limit range from at least 0.2 to 10.0 by increments of 0.1.

6.14A.4 Adjust the low minute volume alarm to 2.0 liters. Turn on the ventilator (with the breathing circuit open) and start a stop watch.

6.14A.5 This step intentionally left blank.

(✓) 6.14A.6 What is the time when APNEA-VOLUME appears as a Caution? ___ sec (26-34)

(✓) 6.14A.7 What is the time when APNEA-VOLUME appears as a Warning? ___ sec (52-68)

(✓) 6.14A.8 Within one (1) minute, does the MINUTE VOLUME LOW message appear as a Caution? ___ Y

6.14A.9 Insert a test minute volumeter in between the absorber and the exhalation valve.

6.14A.10 Reconnect the ventilator hose to the Ventilator Hose terminal.

6.14A.11 Adjust the FREQUENCY to 6 BPM.

6.14A.12 Adjust the I:E RATIO to 1:2.

6.14A.13 Adjust the flow to the maximum of the LOW zone.

6.14A.14 Adjust the oxygen flow to 2 l/min.

6.14A.15 Adjust the Tidal Volume to 200 ml.

6.14A.16 After the first breath is detected, do the APNEA-VOLUME Warning message and the MINUTE VOLUME LO Caution message deactivate? ___ (Y)

6.14A.17 Adjust the low alarm limit above the indicated minute volume.

6.14A.18 Does the MINUTE VOLUME LO message appear as a Caution? ___ (Y)

6.14A.19 Adjust the low alarm limit below the indicated minute volume.

6.14A.20 Does the MINUTE VOLUME LO Caution message deactivate? ___ (Y)

6.14A.21 Increase the tidal volume to 1000 ml and the frequency to 10 BPM.

6.14A.22 Press the O_2 Flush momentarily to inflate the bellows.

6.14A.23 Readjust the inspiratory flow as necessary to fully collapse the bellows.

(✓) 6.14A.24 Are the tidal and minute volumes on the machine and on the test volumeter within 20% of each other? ___ (Y)

6.14A.25 Create a reverse flow by loosening the expiratory valve dome. Remove the breathing hose from the flow sensor. Connect a test terminal and a Riken aspirator (negative pressure squeeze bulb) to the 22 mm male port of the flow sensor. Disconnect the hose attached to the exhalation valve. Compress and release the aspirator.

(✓) 6.14A.26 Each time a reverse flow greater than 20 ml is detected, does the REVERSE FLOW message appear as an Advisory? ___ (Y)

6.14A.27 Tighten the expiratory valve dome. Remove the test terminal and aspirator from the flow sensor and reconnect the patient circuit hose. Reconnect the hose between the expiratory valve and the flow sensor.

6.14A.28 Disconnect the respiratory volume sensor cord from the VOLUME SENSOR interface.

6.14A.29 Do the VOL SENSOR DISC appear as an Advisory, and is LED illuminated in the Breathing Volume OFF key? ___ (Y)

6.14A.30 Connect the respiratory volume sensor cord to the VOLUME SENSOR interface and verify that the alarms clear.

6.15 Ventilator Test

6.15.1 Set the Man/Auto selector to BAG.

6.15.2 Set the FREQUENCY to 10 BPM.

6.15.3 Set the I:E RATIO to 1:2.

6.15.4 Set the Tidal Volume to 1000 ml.

6.15.5 Attach a patient circuit to the absorber system.

6.15.6 Adjust the O_2 flow to 3 l/min.

6.15.7 Turn the ventilator on.

6.15.8 Verify the FAULT indicator turns on (Y)

6.15.9 Set the Man/Auto selector switch to AUTO.

6.15.10 Verify the FAULT indicator turns off (Y)

6.15.11 Adjust the INSPIRATORY FLOW to the maximum of the LOW zone.

6.15.12 Occlude the Y-piece with your thumb.

6.15.13 What is the peak inspiratory pressure? ___ cm H_2O (>30 cm H_2O)

6.15.14 Attach a 3-liter bag to the Y-piece.

6.15.15 Using a stopwatch, time the inspiratory phase.

6.15.16 What is the inspiratory time? ___ seconds (1.8 - 2.2)

6.15.17 Using a stopwatch, time the expiratory phase.

6.15.18 What is the expiratory time? ___ seconds (3.6 - 4.4)

6.15.19 Press and hold the EXTENDED RANGE switch and scroll the I:E ratio dial counter clockwise and verify the extended I:E ratio values increment (2:1, 3:1 and 4:1); return the I:E ratio to 2:1.

6.15.20 Using a stopwatch, time the inspiratory phase.

6.15.21 What is the inspiratory time? ___ seconds (3.6 - 4.4)

6.15.22 Using a stopwatch, time the expiratory phase.

6.15.23 What is the expiratory time? ___ seconds (1.8 - 2.2)

6.15.24 Adjust the FREQUENCY and I:E RATIO through the following settings and verify that the ventilator cycles properly:

FREQ.	I:E RATIO	FREQ.	I:E RATIO
11	1:1	66	1:3.5
22	1:1.5	77	1:4
33	1:2	88	1:4.5
44	1:2.5	99	1:4.5
55	1:3		

6.16 Bellows Drive Gas Leak Test

6.16.1 Remove the ventilator hose from the VENTILATOR HOSE terminal on the bellows.

6.16.2 Attach a test terminal to the bellows assembly ventilator hose terminal.

6.16.3 Connect a flowmeter test stand (P/N S000081) to the test terminal.

6.16.4 Set the FREQUENCY to 1 BPM.

6.16.5 Set the I:E RATIO to 1:1.

6.16.6 Set the INSPIRATORY FLOW to the maximum.

6.16.7 Turn the ventilator on.

6.16.8 What is the flow that is indicated during the inspiratory phase? ___ (<50 ml)

6.16.9 Remove the test terminal and flowmeter test stand. Reconnect the ventilator hose to the VENTILATOR HOSE terminal.

6.17 "F" Bellows Test

6.17.1 Set the FREQUENCY to 10 BPM.

6.17.2 Set the I:E RATIO to 1:2.

6.17.3 Adjust the O_2 flow to 300 ml.

6.17.4 Adjust the INSPIRATORY FLOW to MED.

6.17.5 Adjust the Tidal Volume to 200 ml.

6.17.6 What is the Tidal Volume on the Omicron monitor? ___ ml (125-250)

6.17.7 Adjust the Tidal Volume to 1000 ml.

6.17.8 What is the Tidal Volume on the Omicron monitor? ___ ml (900-1100)

6.17.9 Adjust the INSPIRATORY FLOW to HIGH.

6.17.10 Adjust the O_2 flow to 5 l/min.

6.17.11 Adjust the Tidal Volume to maximum.

6.17.12 What is the Tidal Volume on the Omicron monitor? ___ ml (_1400)

6.18 Ventilator Relief Valve Test

6.18.1 Adjust the O_2 flow to 10 l/min.

6.18.2 Adjust the INSPIRATORY FLOW to MED.

6.18.3 Adjust the I:E RATIO to 1:3, and the FREQUENCY to 10.

6.18.4 Adjust the Tidal Volume to 1200 ml.

6.18.5 What is the PEEP? ___ cm H_2O ($\leq$3)

6.18.6 Adjust the O_2 flow to 500 ml.

6.18.7 Does the ventilator deliver the full Tidal Volume during the inspiratory time? ___ (Y)

6.18.8 Does the bellows stop adjust smoothly? ___ (Y)

6.19 Inspiratory Pressure Limit Test

6.19.1 Set the Inspiratory Flow to the middle of the medium range.

6.19.2 Set the oxygen flow rate to 4 l/min.

6.19.3 Set the Pressure Limit Control to its MIN position.

6.19.4 Occlude the Y-piece with your thumb.

6.19.5 What is the peak pressure? ___ cm H_2O (<15)

6.19.6 Adjust the Pressure Limit Control to 30.

6.19.7 What is the peak pressure? ___ cm H_2O (27-33)

6.19.8 Turn the pressure limit control clockwise to the MAX setting.

6.19.9 What is the peak pressure? ___ >40 cm H_2O

6.19.10 Remove your thumb from the Y-piece.

6.19.11 Set the Inspiratory Flow to the maximum of the LOW zone.

6.19.12 Close the oxygen flow control valve.

6.19.13 Turn the ventilator OFF. NOTE: The inspiratory flow gauge will not return to the stop position when the ventilator is turned off.

6.20 Oxygen Concentration Test

6.20.1 Oxygen + Nitrous Oxide Concentration Test

6.20.1.1 Turn the SYSTEM POWER switch to ON.

6.20.1.2 Disconnect the pipeline supplies

6.20.1.3 Open the APL valve.

6.20.1.4 Connect a 12-inch hose between the inspiratory valve and the expiratory valve.

6.20.1.5 Set the Man/Auto selector to BAG.

6.20.1.6 Occlude the bag mount.

6.20.1.7 Insert the sensor from a calibrated Omicron monitor into the valve dome adapter on the inspiratory valve.

6.20.1.8 Close all the flow control valves.

6.20.1.9 Open one (1) cylinder valve for each gas.

6.20.1.10 Depress the O_2 FLUSH button for 15 seconds.

6.20.1.11 Set the oxygen flow to 4 l/min.

6.20.1.12 Does the Omicron monitor read 97-100% within 3 minutes? ___ (Y)

6.20.1.13 Set the nitrous oxide flow to 2 l/min.

6.20.1.14 What is the oxygen concentration after 3 minutes? ___ % (64-70)

6.20.1.15 Close the nitrous oxide flow control valve.

6.20.2 Oxygen + Air Concentration Test - If Applicable

6.20.2.1 Depress the O_2 FLUSH button for 15 seconds.

6.20.2.2 Does the Omicron monitor read 97-100% within 3 minutes? ___ (Y)

6.20.2.3 Set the air flow to 2 l/min.

6.20.2.4 What is the oxygen concentration after 3 minutes? ___ % (71-77)

6.20.2.5 Close the air flow control valve.

6.21 Oxygen Ratio Control (ORC) Test

6.21.1 Open the oxygen and nitrous oxide cylinder valves.

6.21.2 Depress the O_2 FLUSH for 15 seconds.

6.21.3 Set the oxygen flow to 1000 ml.

6.21.4 Open the nitrous oxide flow control valve to the stop position.

6.21.5 What is the oxygen concentration after 3 minutes? ___ % (21-29)

6.21.6 Adjust the oxygen flow to 1.5 l/min.

6.21.7 What is the oxygen concentration after 3 minutes? ___ % (21-29)

6.21.8 Adjust the oxygen flow to 2 l/min.

6.21.9 What is the oxygen concentration after 3 minutes? ___ % (21-29)

6.21.10 Adjust the oxygen flow to 4 l/min.

6.21.11 What is the oxygen concentration after 3 minutes? ___ % (21-29)

6.21.12 Reduce the O_2 flow to 500 ml/min. Verify that the N_2O flow is greater than or equal to 600 ml/min.

6.21.13 Slowly close the oxygen flow control valve.

6.21.14 What is the oxygen concentration with the O_2 flow control valve closed? ___% (>21%)

6.21.15 What is the flow of nitrous oxide? ___ ml/min. (375-750 ml/min.)

6.21.16 Close the nitrous oxide flow control valve.

6.22 Oxygen Flush and 100% O2 Final Test

6.22.1 Close the nitrous oxide cylinder valve.

6.22.2 Turn the SYSTEM POWER switch to ON.

6.22.3 Set the oxygen flow rate to 5 l/min.

6.22.4 Fully open the nitrous oxide flow control valve.

6.22.5 After the nitrous oxide flow stops, close the N_2O flow control valve.

6.22.6 Close the oxygen flow control valve.

6.22.7 Close the additional gas(es) cylinder valves.

6.22.8 Bleed the gas from the additional gas circuit(s).

6.22.9 Turn the SYSTEM POWER switch to STANDBY.

6.22.10 Press and release the O_2 FLUSH button.

6.22.11 Does the flow of oxygen stop immediately? __ (Y)

6.22.12 Connect a test minute volumeter (P/N 2212300) to the common gas outlet, using the Fresh Gas Outlet Volume Test Device (P/N S010158).

6.22.13 Press and hold the O_2 FLUSH button for 6 seconds.

6.22.14 What is the oxygen flush flow rate? ___ l/min. (4.5-6.5)

6.22.15 Remove the test minute volumeter and test fixture, and reconnect the fresh gas hose.

6.22.16 Turn the SYSTEM POWER switch to ON.

6.22.17 Insert the calibrated sensor into the inspiratory valve dome.

6.22.18 Press the O_2 FLUSH button.

6.22.19 What is the O_2 concentration after 3 minutes? ___ % O_2 (97-100)

6.22.20 Remove the sensor and install the plug.

6.22.21 Close the oxygen cylinder valve.

6.22.22 Bleed the oxygen circuit by pressing the O_2 FLUSH button.

6.23 Scavenger Interface, A/C

6.23.1 Remove all scavenger hoses one at a time, and drain all accumulated moisture. Inspect all scavenger hoses for deterioration and replace any worn hoses.

6.23.2 Remove the safety relief valve housing by unscrewing it in a counterclockwise direction.

6.23.3 Inspect the rubber O-ring and replace if worn.

6.23.4 Remove the safety relief valve from its housing by twisting it out in a counterclockwise direction. The tips of needle-nose pliers can be used to turn the valve. Be careful not to damage the valve disk.

6.23.5 Remove any accumulated lint or dust from the valve with a soft brush. The valve may be further cleaned with a low flow of clean air or oxygen. The scavenger body can be cleaned with a moist cloth.

6.23.6 Reinstall the valve into the housing, making sure that it is threaded all the way into the housing and that the plastic washer is properly seated on its upper surface.

6.23.7 Make sure that the interior of the valve body is completely dry. Reinstall the valve housing onto the scavenger body, making sure that the O-ring is properly seated.

6.23.8 Perform the following Pre-use Checkout procedure:

6.23.8.1 Connect a 19 mm scavenger hose between the bottom of the absorber pole and the right-hand port on the scavenger. Connect a short 19 mm scavenger hose between the APL valve and the port on the rear of the absorber pole. Connect a 19 mm scavenger hose between the ventilator relief valve and the left-hand port on the scavenger.

6.23.8.2 Connect a short 22 mm breathing hose from the inspiratory valve to the expiratory valve on the absorber.

6.23.8.3 Set the Man/Auto valve to the AUTO position.

6.23.8.4 Set the oxygen flow to 10 l/min. and occlude the 19 mm scavenger terminal labeled EXHAUST.

6.23.8.5 After the ventilator bellows inflates, the flow of oxygen will exit the system through the positive pressure safety relief valve. At this point, the absorber system breathing pressure gauge shall indicate a pressure of 10.0 cm H_2O or less.

6.24 Open Reservoir Scavenger

6.24.1 Remove all scavenger hoses one at a time and drain all accumulated moisture. Inspect all scavenger hoses for deterioration and replace any worn hoses.

6.24.2 Disconnect the hospital vacuum source from the scavenger.

6.24.3 Remove the scavenger mounting screws.

6.24.4 Remove the two screws securing the access panel at the bottom of the scavenger canister.

6.24.5 Remove and inspect the silencer; replace if needed.

6.24.6 Remove the reservoir canister from the scavenger body by unscrewing the four socket head cap screws located at the top of the canister.

6.24.7 Remove the flowmeter from its housing by turning it counterclockwise. Inspect the tube and clean with compressed air if needed.

6.24.8 Reassemble the scavenger assembly, and reactivate the vacuum source.

6.24.9 Perform the following negative pressure relief test:

6.24.9.1 Connect a 19 mm scavenger hose between the bottom of the absorber pole and the right-hand port on the scavenger. Connect a 19 mm scavenger hose between the APL valve and the rear port on the absorber pole. The left-hand scavenger port may be capped for this test, or may be connected to the ventilator relief valve. Connect a DISS vacuum hose to the threaded terminal on the left side of the scavenger. Alternatively, an adapter can be used to attach a wall suction hose to the hose barb fitting on the adapter.

6.24.9.2 Connect a short 22 mm breathing hose from the inspiratory valve to the expiratory valve on the absorber. Set the Man/Auto selector valve to the BAG position. Turn the APL valve control knob fully counterclockwise.

6.24.9.3 Verify that the suction waste gas disposal system is active.

6.24.9.4 Adjust the scavenger needle valve until the flowmeter indicates between the white lines. Close all flow control valves on the anesthesia machine. Occlude the absorber breathing bag terminal.

6.24.9.5 Install a scavenger adapter with a hose barb between the 19 mm hose terminal of the scavenger, and the scavenger hose. Connect a test pressure monitor to the hose barb on the adapter and observe the pressure reading on the test gauge. The gauge shall indicate a pressure of 0 cm H_2O.

6.24.10 Perform the following positive pressure relief test:

6.24.10.1 Connect a 19 mm scavenger hose between the bottom of the absorber pole and the right-hand port on the scavenger. Connect a 19 mm scavenger hose between the APL valve and the rear port on the absorber pole. The left-hand scavenger port may be capped for this test, or may be connected to the ventilator relief valve. Connect a DISS vacuum hose to the threaded terminal on the left side of the scavenger. Alternatively, an adapter can be used to attach a wall suction hose to the hose barb fitting on the adapter.

6.24.10.2 Connect a short 22 mm breathing hose from the inspiratory valve to the expiratory valve on the absorber. Set the Man/Auto selector valve to the BAG position. Turn the APL valve control knob fully counterclockwise.

6.24.10.3 Verify that the suction waste gas disposal system is active.

6.24.10.4 Turn the scavenger needle valve fully clockwise (closed).

6.24.10.5 Open the oxygen flow control valve on the anesthesia machine to a flow of 10 l/min. and occlude the absorber breathing bag terminal.

6.24.10.6 The flow of oxygen shall now exit the system through the relief ports around the top of the canister. The test pressure gauge shall indicate a pressure less than 1.0 cm H_2O.

6.24.10.7 After the test, adjust the scavenger needle valve for a flowmeter indication halfway between the two white lines.

6.25 Suction Regulator (if applicable)

6.25.1 Verify that the suction bottle is attached to the suction regulator.

6.25.2 Verify that vacuum is attached to the ¾ in. DISS vacuum connection.

6.25.3 Set the vacuum on/off valve to the OFF (vertical) position.

6.25.4 Connect a digital pressure meter to the collecting inlet stem of the suction bottle.

6.25.5 Set the digital pressure meter to the mmHg scale.

6.25.6 Turn the vacuum control knob fully counter-clockwise.

6.25.7 What is the vacuum indicated on the digital pressure meter? (0)

6.25.8 Turn the vacuum control knob fully clockwise and verify that the vacuum control knob stops.

6.25.9 Set the vacuum on/off valve to the ON position.

6.25.10 Set the regulator to indicate 250 mmHg.

6.25.11 What is the vacuum indicated on the digital pressure meter? (200-300 mmHg)

6.25.12 Return all controls to their original positions.

6.26 Final Check

6.26.1 Verify that the pipeline hoses are connected to the hospital pipeline.

6.26.2 Verify that the APL valve knob is turned completely counterclockwise, fully open.

6.26.3 Place the Auto/Man selector in the BAG position.

6.26.4 Verify that the oxygen sensor is removed from the valve dome adapter.

6.26.5 Verify that the valve dome is plugged.

6.26.6 Verify that the machine is plugged into a live outlet.

6.26.7 Return all machine controls and settings to their original state.

6.26.8 Carefully inspect the machine to verify that no loose screws, washers, or tools are left on or in any part of the machine.

7

Imaging Test Protocol

Section contents:

Test Setup

Three (3) procedures must be performed before the Narkomed MRI is put into service in the MRI scanning room:

- Power supply filter box installed on MRI room access panel
- Narkomed MRI PMC completed (pass all conditions)
- Imaging Test Protocol (pass all scans)

The purpose of these tests is to verify that the Narkomed MRI does not interfere with the diagnostic quality of the MR images.

NOTE: If any of these procedures are not successfully completed during the initial setup of the machine, do not remove label “Warning Do Not Use or Place...” (Part # 4115245) from the flowmeter shield. Review the status of the setup and installation procedure and the recommendations, with the customer. Also, complete a “WARNING THIS MACHINE IS NOT CERTIFIED” label (P/N 4114857) and place it at a prominent location on the right side of the machine. Ensure that the “General Comments” on the PMC form and ”Executive Summary” fields indicate the condition and reason why the machine is not certified. Some examples are:

- P/S filter not installed: “Power supply filter not installed at time of machine setup”
- Incomplete ITP: “ITP incomplete at time of machine setup”
- Failed ITP: “The Imaging Test Protocol does not indicate a pass condition”

Imaging Test Protocol (ITP)
Overview:

An ITP is required to complete the installation and approximately 30 minutes of magnet time is needed. The ITP consists of five (5) scans, described as follows:

Type of scans: 4 scans, 2-Dimensional Spin Echo (2DSE)
1 scan, customer choice

1. The first scan is performed after the filter box is installed on the access panel, with the anesthesia machine outside the MRI room and with a **head coil/phantom**. This is a base line scan to verify the room integrity.

2. The next scan, again with the **head coil** is performed with the machine in the MRI room in a position typical of where it is used clinically.

3. The third scan is a base line scan with a **body coil**, with the machine outside the MRI room.

4. The fourth scan, again with the body coil, and with the machine in the MRI room in a position typical of where it is used clinically.

5. The fifth scan shall be any type chosen by the MRI technician. The scan shall be performed using any type of phantom coil, with the machine in the MRI room in a position typical of where it is used clinically.

The TSR shall record the results of these imaging tests on the ITP form and checklist (see following pages), as determined by the hospital MRI technician.

Scan Sequence:

Scan 1: Disconnect the power cable from the rear of the machine. Move the Narkomed MRI outside the scanner room. Perform the first scan (re: overview) and verify with the MRI technician that the imaging system is performing to its specifications with acceptable image quality. Record the Service Protocol and results on the ITP form shown on Page 7-5.

NOTE: Recheck the installed Narkomed MRI system for obvious installation errors if the tests are not passed.

Scan 2: Move the Narkomed MRI inside the scanner room to a position typical of where it would be used clinically. Lock the casters and connect the energized thirty (30) foot cable to the Narkomed MRI.

If pipeline gas and wall suction are available in the scanner room, attach the gas and suction line(s) to the Narkomed MRI.

Apply power to the Narkomed MRI using the main switch on the front of the anesthesia machine. Verify that the monitor and ventilator successfully complete the power on lamp test. Verify that the AC Fail lamp on the alarm channel is not lighted.

Perform an O_2 cell calibration. Set the ventilator to 10 BPM with an I:E ratio of 1:1. Turn on the ventilator.

Perform Scan (re: overview) and verify with the MRI technician that the imaging system is performing to its specifications with acceptable image quality. Record the Service Protocol and results on the ITP form.

Scan 3: Perform Scan (re: overview) and verify with the MRI technician that the imaging system is performing to its specifications with acceptable image quality. Record the Service Protocol and results on the ITP form.

Scan 4: Perform Scan (re: overview) and verify with the MRI technician that the imaging system is performing to its specifications with acceptable image quality. Record the Service Protocol and results on the ITP form.

Scan 5: Perform Scan (re: overview) and verify with the MRI technician that the imaging system is performing to its specifications with acceptable image quality. Record the Service Protocol and results on the ITP form.

Fill out a copy of the ITP checklist shown on Page 7-7 and mail it with the Imaging Test Protocol form to:

Technical Service Department
Draeger Medical, Inc.
3122 Commerce Drive
Telford, PA 18969-9977

SETUP AND INSTALLATION IMAGING TEST PROTOCOL

Hospital _____

Narkomed MRI Serial # _____

Magnet Center or Resonant Frequency: _____ MHz

Service Protocol Name or Sequence Used (Obtain from hospital MRI operator):

Scan 1:_____

Scan 2:_____

Scan 3:_____

Scan 4:_____

Scan 5:_____

COMMENTS ON IMAGE QUALITY

Scan 1:_____

Scan 2:_____

Scan 3:_____

Scan 4:_____

Scan 5:_____

All Imaging Tests Passed? ____Yes ____No

Installation type (circle one): New machine installation Monitor upgrade Repair

MRI Service Representative or hospital MRI operator (print): _____

Phone Number: _____

NAD Service Representative (sign) _____

Date: _____

Mail copies of this report and the ITP Checklist to:

Technical Service Department
Draeger Medical, Inc.
3122 Commerce Drive
Telford, PA 18969-9977

NM MRI IMAGING TEST PROTOCOL (ITP) CHECKLIST

1. Verify that each side of the filter box is mounted flush with the penetration panel. ____
2. Verify that the voltage measured at the 52' cable connector, that joins the connector on the back of the NM MRI machine, is between +13.6 VDC and +14.5 VDC when measured at Pin 1, referenced to Pin 2. ____
3. Verify that the power supply charger is located outside of the MRI room. ____
4. Verify with the MRI technician that the MRI system at the site is fully functional. ____
5. Have the MRI technician perform a baseline scan using the head phantom. ____
6. Verify with the MRI technician that the NM MRI machine works in conjunction with the MRI system using the head phantom. ____
7. Have the MRI technician perform a baseline scan using the body phantom. ____
8. Verify with the MRI technician that the NM MRI machine works in conjunction with the MRI system using the body phantom. ____
9. Have the MRI technician run any additional scans to confirm that the MRI system is working properly in conjunction with the NM MRI machine. ____
10. Fill out the ITP report and attach this checklist to the ITP. Remember to include the name of the hospital, and to sign and date the report before sending it to NAD. ____

Hospital _____

Narkomed MRI Serial # _____

NAD Service Representative (sign) _____

Date: _____

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Dräger medical

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